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**Term perinatal mortality audit in The Netherlands 2010-2012: a population based cohort study**

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## ABSTRACT

### Objective

To assess the implementation and first results of term perinatal internal audit by a standardised, privacy protected method.

### Design

Cohort study.

### Setting

All hospitals with obstetric-paediatric departments linked to community practices of midwives, general practitioners in their attachment areas, organised in perinatal cooperation groups (PCG).

### Population

943 registered cases of term perinatal mortality occurring in 2010-2012 with detailed information, including 707 cases with completed audit results.

### Main outcome measures

Participation rate in audit, perinatal death classification, identification of substandard factors (SSF), SSF in relation to death, conclusive recommendations for quality improvement in perinatal care and antepartum low risk selection for primary care supervision at start of labour.

### Results

After the introduction of perinatal audit in 2010, all PCG's participated in 2011. In total 20,091 health care professionals participated in 645 audit sessions.

Of all 1102 term perinatal mortality cases (2.3 per 1000) for 86% (943) of cases extensive data are registered and of 64% (707) standardized audit results are documented.

In 53% of the cases at least one SSF was identified. Non-adherence to guidelines (35%) and deviation of usual care (41%) were the most frequent SSF.

In the study period 8% of all audited cases had a probable relation between the SSF and perinatal death. This declined over the years: from 10% in 2010 to 5% in 2012. Simultaneously term perinatal mortality decreased from 2.3 to 2.0 per 1000 births.

Possibilities for improvement were identified in the fields of the organisation of care (35%), content of guidelines or usual care (19%) and of documentation (15%).

Antepartum low risk selection decreased from 21% in 2010 to 16% in 2012.

### Conclusions

Perinatal audit is nationwide implemented in all obstetrical units in the Netherlands in a short time period. It is possible that audit contributed to the decrease of term perinatal mortality.

Strengths and limitations of this study

- The Netherlands is the first country with a nationwide perinatal audit that is now systematically performed by all collaborating perinatal health care professionals at the local level. Within two years all hospitals that provide obstetric/paediatric care with the surrounding and adherent midwifery practices in the country participated in perinatal audit.
- Perinatal audit resulted in description of substandard factors (SSF) and the formulation of many recommendations mostly ready for implementation within the own perinatal cooperation groups.
- Audit by a multidisciplinary team of the health care professionals themselves (internal audit), is a feasible way to increase implementation of the audit results/recommendations in local practice. In the chosen approach in the Netherlands an independent chairperson has proven instrumental to optimize audit performance.
- Not all term cases of perinatal mortality are audited. Characteristics of the audited cases are comparable to all term perinatal mortality cases in the national registration. This suggests that cases have not been avoided systematically or were lost for discussion in the audit. Of all audited cases information was insufficient in 11% for SSF assessment.
- Knowledge of the outcome can influence the judgment of the care and the relation between the substandard factors and the outcome, especially when the outcome is perinatal death.

## Term perinatal mortality audit in The Netherlands 2010-2012: a population based cohort study

### Introduction

Perinatal mortality is an important indicator of the quality of perinatal care.<sup>1</sup> In 2000 The Netherlands had the highest perinatal mortality rate as compared to a large group of European countries.<sup>2 3</sup> Although perinatal mortality in The Netherlands has in later years decreased, in 2010 the ranking relative to other European countries showed only a modest improvement. Research suggests that improving (preventive) care can lead to perinatal health gains.<sup>4 5</sup>

The outcomes of the international benchmarks were an important incentive for Dutch politicians and professionals in the field of perinatal care to investigate the determinants of perinatal mortality including assessment of the quality of care. One of the most suitable procedures in this regard is perinatal audit, a critical and systematic analysis of the quality of perinatal care.<sup>6</sup> The introduction of perinatal audit in Norway has been an important factor in improving the quality of perinatal care and preceded a decline of perinatal mortality in Norway.<sup>7 8 9</sup>

In the Netherlands, perinatal audit studies were undertaken in the eighties of the past century. These audits were local or regional one-time studies.<sup>10 11 12</sup> More recently and with strong support from the government the professional organisations involved have jointly prepared the introduction of a nationwide perinatal mortality audit program that would become a standard part of perinatal care.<sup>13 14 15 16 17</sup> The Foundation Perinatal Audit in the Netherlands (PAN) was set up by the professional organisations of midwives, general practitioners, obstetricians, paediatricians, and pathologists ([www.perinataleaudit.nl](http://www.perinataleaudit.nl)). The first nationwide Dutch perinatal mortality audit has started with the audit of term perinatal mortality.

The objective of this study is to describe the implementation process of perinatal audit and to present the results after the first three years of term perinatal audit: perinatal death classification, antepartum low risk selection (for supervision of the first line at start of labour), identification of substandard (care) factors (SSF), SSF in relation to death and conclusive recommendations for quality improvement in perinatal care.

### Methods

#### *Organization and training*

A regional infrastructure with audit support teams has been set up. The teams consist of health care professionals in the 10 tertiary centres for perinatology with a neonatal intensive care unit (NICU) and obstetric 'high care' department facilities. These regional teams were trained by PAN for coordination and support of the audit performance at local (hospital) levels. Subsequently these

regional teams trained the audit teams of the local hospitals and the surrounding practices of independent community midwives and general practitioners (Perinatal Cooperation Groups) within their region. PAN cooperated with the IMPACT project that pioneered the introduction of perinatal audit in the Northern region of The Netherlands.<sup>18</sup> PAN offered regular training sessions in organisation of audit, in making narratives, in chairing of the audit meeting and in classification of perinatal mortality.

In January 2010 the nationwide Dutch perinatal mortality audit has officially started with the audit of term perinatal mortality as the first topic. Term perinatal mortality was chosen because of the involvement in term pregnancies and deliveries of all professional groups in the obstetric/paediatric/neonatal field. Within The Netherlands community midwives and, on a small scale, general practitioners provide obstetric care to women with antepartum judged low risk profiles. If complications (threaten to) occur the responsibility for obstetric care will be transferred to a medical specialist in a general hospital (secondary care) or tertiary centre. Risk selection during pregnancy and labour in primary or secondary/tertiary care is therefore the essence of the Dutch perinatal care organisation.<sup>19 20</sup>

The Netherlands is divided in 10 perinatal healthcare regions, catchment areas for perinatal high care centres which have NICU facilities. In 2012 there were 90 hospitals with obstetric/paediatric care facilities (97 in 2010 and 93 in 2011). Each hospital and the surrounding community practices of independent midwives and general practitioners are organised in a Perinatal Cooperation Group (PCG). Each PCG is responsible for auditing and registration of the mortality cases in their catchment area.

Representatives of the professionals of the PCG's analyse the cases in a systematic way, identify substandard care factors (SSF) in delivered care and/or organisation of care, identify the types of professionals involved and classify mortality according to three different systems, i.e. the Wigglesworth, ReCoDe and Tulip classifications.<sup>21-23</sup> During the audit the professionals relate the degree (non/unlikely, possible, probable, unknown) to whether the SSF was causative for the death. Specific recommendations for improving the quality of care are then formulated. An independent chairperson presides the audit.

Audit with (involved) professionals is a delicate matter and needs careful procedures. The PAN has developed basic rules to enable a safe environment:

- Everything discussed during the audit is confidential. Every participant signs for this.
- Everybody is expert in his own professional field, participants can question professionals in other fields but not judge them.
- The provided care and cure are assessed by comparing it to formal guidelines or usual care, not by one's own judgment.
- Narratives of the discussed cases that were drawn up before the meeting by members of the PCG are destroyed after the audit.

### Definitions

Term perinatal mortality is defined as stillbirth and neonatal mortality during the first four weeks of life in births with gestational ages from 37.0 weeks onwards.<sup>24</sup> Cases with unknown gestational age were excluded.

A substandard factor (SSF) is defined as a care management problem involving care that deviated from the safe limits of practice as laid down in guidelines, standards, protocols or normal practice.<sup>25</sup>

### Registries

Because the audit focusses on recent cases that require more detailed and up to date information than is present in the national Dutch perinatal registry (PRN), two specific real-time databases were created to support the audit. The first for the registration of perinatal mortality cases to be audited (PRN-Audit) and the second for the confidential registration of the audit process and its outcomes (PARS).

#### PRN-Audit database

Term perinatal mortality cases are registered in PRN-Audit by health care professionals. Data are gathered from the medical records and registered with specific details needed to construct the narrative that will be used during the audit. In PRN-Audit supplemental information is included such as professionals involved in the care process, diagnostics, policy decisions, actions (treatments, referrals) and antepartum low risk selection (for supervision of the first line at start of labour) with their time frames. The audit narrative, the basic document for the audit meeting, is automatically generated from the PRN-Audit database as an anonymous document.

#### PARS database

The audit meetings (participants, number of cases discussed) and the outcomes of the audits are registered by the local audit groups in a separate database PARS.

Because of privacy restrictions and to create a safe and secure environment for audit participants the PARS database is anonymous; only characteristics such as gestational age at birth, time (foetal-neonatal) of death (Wigglesworth classification) and the underlying cause of death category (Tulip classification) are registered in PARS.

#### PRN registry as reference

The standard national PRN registry contains population-based information on all pregnancies, deliveries from 22 weeks onwards and (re)admissions occurring until 28 days after delivery ([www.perinatereg.nl](http://www.perinatereg.nl)). The data are collected by different professionals and are linked 1,5 years afterwards and made available in reports, to researchers and policymakers.<sup>20,26</sup> The completeness of PRN is currently around 96-98% of all births. This national PRN database is the reference source for the audit cases in our study.

### Statistical methods

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The study is descriptive. In comparison of characteristics in the PRN registry with the characteristics in the PRN-Audit/ PARS database a chi-squared test is used.

**Ethical approval**

Anonymous registry data are used, no ethical approval is needed.

The Dutch perinatal registry has given permission for the analysis of their data.

For peer review only



## Results

A total of 943 (86%) cases of term perinatal mortality cases in the period 2010-2012 are registered in the PRN-Audit database and 707 (64%) cases were audited and recorded in the PARS database. Compared to the number of cases in the national perinatal registry PRN, the number of cases that were registered in the PRN-Audit database increased over the years (from 85% in 2010 until 89% in 2012) and the registration of cases in PARS showed an increase of 59% in 2010 to 66% in 2012. (table 1).

### ***Audit meetings and participation in audit of professionals***

Throughout The Netherlands 645 audit meetings took place in 2010-2012 with in total 20,091 participating health care professionals as community (independent) midwives, general practitioners, obstetricians, clinical midwives, nurses, paediatricians, pathologists, registrars, medical students and students in midwifery. The number of participants nearly doubled in 2012 as compared to 2010. Audit participation of the perinatal cooperation groups reached full coverage in the second year (2011) (table 1).

### ***Substandard factors***

In 53% (376) of the 707 audited cases one or more substandard factors (SSF) were identified (table 2). A total of 717 SSF's emerged. In 35% of the cases these were related to not following guidelines (without motivation) or missing appropriate local protocols and in 41 % they implied a deviation of usual care. Examples of deviations of guidelines are: no or delayed consultation of obstetrician in case of suspected foetal growth restriction, no foetal monitoring in case of induction of labour, expectant policy in case of non-reassuring cardiotocography, non-optimal following of the guideline for resuscitation of the new born. Examples of deviation of usual care are: no foetal monitoring in case of vaginal blood loss, no consultation or action undertaken in case of less foetal movements, no further diagnosis and/or action in case of presumed growth restriction and insufficient documentation in the medical records (medication, diagnostic considerations and policy).

### ***Cause of death***

Autopsy was performed in 38% and pathological examination of the placenta in 77% of the term cases registered for audit. Table 3 gives the underlying cause of death using the Tulip classification. In 36 % of cases the cause of death is classified as 'placental' and sub-classified as placental pathology (31%), followed by umbilical cord complications (28%) and placental bed pathology (28%). Congenital malformation was classified in 19% as the underlying cause of death. In 32% of cases the cause of death is unknown.

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***SSF, relation to death and professional involvement***

In 8% (57) of the 707 audited cases the relation of SSF to death was ascertained as probable and in 13% as possible. The probable relation of SSF's to death halved from 10% in 2010 to 5% in 2012 (table 4).

In total 1269 health care professionals played a role in substandard factors in 376 cases: mean 3.4 professionals per case. Of them 26% were obstetrician, 20% independent community midwife and 12% a clinical midwife. Nurses were involved in 10% of the cases, paediatricians in 7% and registrars in 10% of the cases.

***Antepartum low risk assessment***

For 19% (183) of all registered cases there was antepartum low risk assessment, thus primary care supervision at start of labour took place. Antepartum low risk assessment showed a decrease by 24% in 2012 compared to 2010 (from 21 to 16% respectively) (table 5).

***Recommendations from the audit***

In total 603 recommendations are given. In 35 % these were about the organisation of care as well as for cooperation inside and outside the hospital between the different professional groups. In 19% the recommendations were for better use of guidelines and following usual care. The recommendations for guidelines are especially for making or adjusting local protocols. In addition recommendations are given for producing local protocols for usual care. A specific frequently pronounced recommendation was the development of a national guideline for reduced foetal movements. In 15% of cases the recommendations are about better documentation of the care process. The advices for better communication (11%) refers to improvement of communication between professionals in community and hospital care. For training and education (17%) recommendations were formulated, for instance neonatal resuscitation training and cardiotocography interpretation courses.

***Representativeness of the documented and audited cases***

Distribution of gestational age, congenital malformation and foetal-neonatal death are comparable in PARS and PRN (table 6a).

The characteristics of the cases 2010-2012 in PRN-Audit database and in the national PRN database are comparable with regard to the mothers characteristics except for a lower percentage of women with non-Caucasian ethnicity ( $p=0.04$ ) and of lower birth weight  $<2000$  grams ( $p=0.01$ ) (table 6b).

## Discussion

The Netherlands is the first country with a nationwide perinatal audit that is now systematically performed by all collaborating perinatal health care professionals at the local level. Within two years all hospitals that provide obstetric/paediatric care with the surrounding and adherent midwifery practices in the country participated in perinatal audit. It proved feasible to audit and register the results of 64% (707) of all cases of term perinatal mortality, which proved to be a representative sample of all term perinatal mortality cases in the Netherlands. Perinatal audit resulted in description of substandard factors (SSF) and the formulation of many recommendations mostly ready for implementation within the own perinatal cooperation groups. During the three years audit period term perinatal mortality decreased with 13% from 2.3 to 2.0 per 1000 births. The probable relation of SSF's to death halved from 10% of all cases in 2010 to 5% in 2012. Antepartum risk selection for primary care supervision at start of labour showed improvement with decrease from 21% to 16% during the years.

### *Strengths and limitations*

Audit by a multidisciplinary team of the health care professionals themselves (internal audit), is a feasible way to increase implementation of the audit results/recommendations in local practice. In the chosen approach in the Netherlands an independent chairperson has proven instrumental to optimize audit performance.<sup>18</sup>

This study concerns perinatal mortality cases of recent date, the last cases of 2012 were audited in June 2013. Most audits are performed within 3-6 months after death which minimizes the potential loss of knowledge/memory and details of the cases and circumstances that contributed.

Not all term cases of perinatal mortality are audited. Characteristics of the audited cases are comparable to all term perinatal mortality cases in the national registration of the PRN, the registered cases were also comparable except for lesser cases with non-Caucasian ethnicity and lesser cases with birth weight < 2000 gram. This suggests that cases have not been avoided systematically or were lost for discussion in the audit. Of all audited cases information was insufficient in 11% for SSF assessment. This percentage showed a substantial decrease during the years: 14% in 2010 to 9% in 2012.

It is unknown whether all audit meetings take place in the most optimal way. PAN offered therefore regular training sessions in organisation of audit, in making narratives, in chairing of the audit meeting and in classification of perinatal mortality.

The cause of death according to the Tulip Classification was classified as unknown in 32% of the cases. This high percentage suggests that improvement may be possible/feasible by further training of the audit teams in using the Tulip classification besides the desirability of more autopsies.<sup>23;27</sup>

Knowledge of the outcome can influence the judgment of the care and the relation between the substandard factors and the outcome, especially when the outcome is perinatal death.<sup>28 29</sup> However, for improvement of the quality of care the identification of substandard care by auditing perinatal mortality cases provides important observations for quality of care improvement.<sup>9</sup>

**Comparison with other studies**

There are no other studies with national internal perinatal audit programs, so we can only compare with earlier regional studies, most of them performed in The Netherlands.

**SSF**

The outcomes of the assessment of SSF's in this study are comparable with the outcomes of previous regional studies in The Netherlands<sup>10-12</sup>, European regions<sup>1</sup> and a regional study in Norway.<sup>9</sup>

In 36% of the audited cases in our study the audit group did not identify or assess any SSF. This is lower than in earlier regional studies in the Netherlands in 1996-1997 and 2003-2004 with 40-45%.<sup>12;15</sup> A possible explanation is that professionals are more critical about their own delivered care than external audit panels are.<sup>29</sup>

In 11% of all cases insufficient information was present for SSF assessment. In earlier audit studies in The Netherlands this percentage was 2-4%.<sup>12;15</sup> However, these audits (and narratives) were prepared by one or two dedicated researchers while in the nationwide audit each perinatal cooperation group has to gather all information for the narrative during their daily work.

**SSF and relation to death**

The audit groups found a probably relation of substandard factors to death in 8% (n=57) of all discussed term perinatal mortality cases. In the LPAS-study, a regional audit study in 2003-2004 in the Netherlands, this was 9%.<sup>15</sup> In earlier studies (external audits) only the combined outcome of possible and likely relation is given: in 25-30% of all cases a possible or likely relation is found between SSF and perinatal mortality in The Netherlands and even 46% in 10 European regions in 1993-1998 (Euronatal study).<sup>1;11;12;30</sup> These percentage were higher than in our recent study (21%) and in the earlier LPAS-study (19%).<sup>15</sup> In the Euronatal study the percentage of cases with such suboptimal care factors was significantly lower in the Finnish (32%) and Swedish (36%) regions compared with the remaining regions.

### ***Implications of the study and further research***

A systematic method of perinatal audit has been implemented by all perinatal cooperation groups in The Netherlands. Audits generated many recommendations for quality of care improvements, which are in progress towards implementation. The foundation for perinatal audit is laid in The Netherlands and more topics can be chosen for audit in perinatal care as preterm mortality or specific morbidity (for instance severe neonatal asphyxia or severe maternal morbidity).

It is assumed that the chance of uptake of actions formulated by local professionals themselves is greater than the uptake of top down imposed advice. In general the implementation of changes in care proves to be difficult.<sup>31</sup> At national level the professional organizations involved now cooperate in the college perinatal care (CPZ), instituted by the Ministry of Health

(<http://www.collegepz.nl/organisatie>). CPZ is coordinating desirable changes in perinatal care.

During the three years studied term perinatal mortality decreased. The probable relation with SSF to perinatal death decreased and risk selection improved. Although a direct relationship cannot be proved, the parallel with the synchrony of audit implementation and subsequently declining perinatal mortality in Norway is striking.<sup>9</sup>

Term perinatal mortality cases who were antepartum selected as low risk (with start of labour occurring under primary care supervision), decreased by a quarter during the years 2010-2012.

This can suggest that risk selection became more accurate and this needs further investigation.

<sup>32</sup>

Some recommendations from the audits have already been implemented such as the need for developing a new national guideline for 'reduced fetal movements'.<sup>33</sup>

### ***Conclusion***

Within a short time period a systematic method of internal perinatal audit has been implemented by all perinatal cooperation groups in The Netherlands. Audits performed by healthcare professionals themselves generated many recommendations for quality of care improvements which are in progress towards implementation. It is possible that audit contributed to the decrease of term perinatal mortality. With ongoing audits quality of perinatal care can be continuously monitored and instruments for quality of care improvement developed.

These findings can be a stimulus for introduction of nationwide internal perinatal audit in other countries.

Table1 Term perinatal mortality cases and audit implementation parameters 2010-2012

	2010		2011		2012		2010-2012	
	n	%	n	%	n	%	n	%
term born children (PRN)	163,276		163,248		160,714		487,238	
mortality cases and rate (PRN)	379	0.23%	398	0.24%	325	0.20%	1102	0.23%
fetal	249	0.15%	252	0.15%	217	0.14%	718	0.15%
neonatal	130	0.08%	146	0.09%	108	0.07%	384	0.08%
term mortality cases in PRN-Audit	324	85%	329	83%	290	89%	943	86%
term mortality cases in PARS	222	59%	272	68%	213	66%	707	64%
perinatal cooperation groups (PCG)	97		93		90		-	
audit participation of PCG	94	97%	93	100%	90	100%	-	
meetings	149		244		252		645	
participants	4,291		7,557		8,243		20,091	

**Table 2a number substandard factor (SSF) per case in term in perinatal mortality 2010-2012**

	n	%
no SSF	252	36%
≥ 1 SSF	376	53%
insufficient information	79	11%
<b>Total cases</b>	<b>707</b>	<b>100%</b>

**Table 2b category of all SSF 's in term perinatal mortality 2010-2012**

Category SSF	n	%
guidelines	250	35%
usual care	294	41%
other	173	24%
<b>Total SSF</b>	<b>717*</b>	<b>100%</b>

\*per case more SSF's can be present

Table 3 Tulip-classification of term perinatal mortality cases by main group and placental subgroup (2010-2012)

Tulip classification			
2010-2012			
	n	%	
Congenital anomaly	135	19%	
<b>Placenta *</b>	<b>253</b>	36%	
Infection	32	5%	
Other	52	7%	
Unknown	224	32%	
no information	11	2%	
<b>Total</b>	<b>707</b>	100%	

  

Placenta*		n	
Umbilical cord complication		70	28%
Placental bed pathology		71	28%
Placental pathology			31%
Development		42	17%
Parenchyma		31	12%
Localisation		6	2%
Not otherwise specified		33	13%
<b>Total</b>		253	100%



**Table 4 Substandard factors (SSF) and relation to death in term perinatal mortality (2010-2012)**

relation to death	n	%
cases with SSF	376	53%
none/unlikely	183	26%
possible	92	13%
<b>Probable*</b>	57	8%
unknown	44	6%
cases without SSF	252	36%
cases with insufficient information	79	11%
Total cases	707	100%
<b>probable relation to death per year*</b>		
2010	23	10%
2011	24	9%
2012	10	5%
2010-2012	57	8%

Table 5 Care type supervision at start of labour and period of death in term perinatal mortality 2010-2012

	perinatal death		foetal death		neonatal death	
Care type supervision at start of labour	n	%	n	%	n	%
primary care*	183	19%	101	11%	82	9%
secondary/tertiary care	730	77%	508	54%	222	24%
unknown	30	3%	4	0%	26	3%
Total	943	100%	613	65%	330	35%

  

primary care*	n	%
2010	68	21%
2011	69	21%
2012	46	16%
2010-2012	183	19%

Table 6a Characteristics of term perinatal mortality PARS versus PRN 2010-2012

	PARS		PRN		p-value*
	n	%	n	%	
gestational age (weeks)					0.91
37.0-40.6	598	85%	930	84%	
≥41.0	109	15%	172	16%	
congenital malformations	135	19%	238	22%	0.20
moment of death					0.40
foetal	447	63%	718	65%	
neonatal	260	37%	384	35%	

Table 6b Characteristics of term perinatal mortality PRN-Audit versus PRN 2010-2012

	PRN-Audit		PRN		p-value*
	n=	943	n=	1102	
Characteristics	n	%	n	%	p-value*
parity 0	450	48%	536	49%	0.68
age mother (years)					
<20	6	1%	11	1%	0.37
≥35	243	26%	292	26%	0.71
non-Caucasian ethnicity	185	20%	257	23%	<b>0.04</b>
congenital malformation	194	21%	238	22%	0.57
Period of death					0.94
foetal	613	65%	718	65%	
neonatal	330	35%	384	35%	
birth weight (grams)					
<2000	30	3%	60	5%	<b>0.01</b>
2000-2499	85	9%	98	9%	0.92
≥4500	22	2%	22	2%	0.60
gestational age (weeks)					
37.0-39.6	579	61%	707	64%	0.20
40.0-41.6	341	36%	371	34%	0.12
≥42.0	23	2%	24	2%	0.69

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[Contributors]

Adja Waelput, Martine Eskes (guarantor), Jan Jaap Erwich, Hens Brouwers, Anita Ravelli, Peter Achterberg, Hans Merkus and Hein Bruinse had the core idea for this study. Anita Ravelli and Martine Eskes prepared and analysed the data and/or interpreted the results. Adja Waelput, Martine Eskes and Anita Ravelli wrote the draft of the article. Jan Jaap Erwich, Hens Brouwers, Peter Achterberg, Hans Merkus and Hein Bruinse commented on the manuscript and approved the final version.

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[Competing interest]

All authors have completed the Unified Competing Interest form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare: there was no support from any organisation for the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

[Ethical approval]

Anonymous registry data are used, no ethical approval is needed.

The Dutch perinatal registry has given permission for the analysis of their data.

[Datasharing]

Dataset can be requested at the board of Foundation Perinatal Audit in the Netherlands (PAN) [info@perinataleaudit.nl](mailto:info@perinataleaudit.nl). Consent was not obtained, data are anonymized.

[Transparency declaration]

Martine Eskes (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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For peer review only



STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	v
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	v
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	v
Objectives	3	State specific objectives, including any prespecified hypotheses	v
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	v
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	v
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed	v
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	v
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	v
Bias	9	Describe any efforts to address potential sources of bias	v
Study size	10	Explain how the study size was arrived at	v
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	v
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed (e) Describe any sensitivity analyses	v n.a. n.a. n.a. n.a.
<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	v n.a. n.a.
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	v v v
Outcome data	15*	Report numbers of outcome events or summary measures over time	v
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which	n.a.

		confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	v
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n.a.
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n.a.
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	v
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	v
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	v
Generalisability	21	Discuss the generalisability (external validity) of the study results	v
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	v

\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.

# BMJ Open

## Term perinatal mortality audit in The Netherlands 2010-2012: a population based cohort study

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**Term perinatal mortality audit in The Netherlands 2010-2012: a population based cohort study**

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Keywords: perinatal audit, perinatal care, term perinatal mortality, quality of perinatal care, substandard care factors, antepartum risk selection.

Wordcount: 3696

## ABSTRACT

### Objective

To assess the implementation and first results of term perinatal internal audit by a standardised method.

### Design

Cohort study.

### Setting

All 90 Dutch hospitals with obstetric-paediatric departments linked to community practices of midwives, general practitioners in their attachment areas, organised in perinatal cooperation groups (PCG) participated in the study.

### Population

The population consisted of 943 registered cases of term perinatal death occurring in 2010-2012 with detailed information, including 707 cases with completed audit results.

### Main outcome measures

Participation in audit, perinatal death classification, identification of substandard factors (SSF), SSF in relation to death, conclusive recommendations for quality improvement in perinatal care and antepartum risk selection at start of labour.

### Results

After the introduction of perinatal audit in 2010, all PCG's participated. They organised 645 audit sessions, with an average of 31 health care professionals per session.

Of all 1102 term perinatal deaths (2.3 per 1000) data were registered for 86% (943) and standardized anonymized audit results for 64% (707).

In 53% of the cases at least one SSF was identified. Non-compliance to guidelines (35%) and nonobservance of usual care (41%) were the most frequent SSF.

There was a probable relation between the SSF and perinatal death for 8% of all cases. This declined over the years: from 10% (n=23) in 2010 to 5% (n=10) in 2012 (p=0.060). Simultaneously term perinatal mortality decreased from 2.3 to 2.0 per 1000 births (p<0.00001).

Possibilities for improvement were identified in the organisation of care (35%), guidelines or usual care (19%) and in documentation (15%).

More pregnancies were antepartum selected as high risk, 70% in 2010 and 84% in 2012 (p=0.001).

### Conclusions

Perinatal audit is nationwide implemented in all obstetrical units in The Netherlands in a short time period. It is possible that audit contributed to the decrease in term perinatal mortality.

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Strengths and limitations of this study

- The Netherlands is the first country in which all collaborating perinatal health care professionals nationwide participate in an internal perinatal audit systematically performed at the local level.
- Within two years all hospitals in the country providing obstetric/paediatric care with their surrounding midwifery practices participated in perinatal audit.
- Perinatal audit resulted in description of substandard factors (SSF), relation to death and the formulation of many recommendations mostly ready for implementation.
- Not all term perinatal deaths are audited. Characteristics of the audited cases are comparable to all term perinatal mortality cases in the national registration.
- Of all audited cases information was insufficient in 11% for substandard factor assessment. This is a major point of attention for the next years.

## Introduction

Perinatal mortality is an important indicator of the quality of perinatal care.<sup>1</sup> In 2000 The Netherlands had the highest perinatal mortality rate when compared to a large group of European countries.<sup>2,3</sup> Although perinatal mortality in The Netherlands has decreased in later years, in 2010, the ranking relative to other European countries showed only a modest improvement<sup>4,5</sup>

These outcomes of the international benchmarks were an important incentive for Dutch politicians and professionals in the field of perinatal care to investigate the determinants of perinatal mortality including assessment of the quality of care. One of possible interventions in this regard is the introduction of perinatal audit, a critical and systematic analysis of the quality of perinatal care.<sup>6</sup> Earlier the introduction of perinatal audit in Norway has been an important factor in improving the quality of perinatal care and preceded a decline of perinatal mortality in Norway.<sup>7-9</sup>

In the Netherlands, perinatal audit studies were undertaken in the eighties of the past century. These audits were local or regional one-time studies.<sup>10-12</sup> More recently the professional organisations involved have jointly prepared the introduction of a nationwide perinatal mortality audit program that would become a standard part of perinatal care.<sup>13-17</sup> The Foundation Perinatal Audit in the Netherlands (PAN) was set up by the professional organisations of midwives, general practitioners, obstetricians, paediatricians, and pathologists ([www.perinataleaudit.nl](http://www.perinataleaudit.nl)). The first nationwide Dutch perinatal mortality audit has started in the period 2010-2012 with the focus on audit of term perinatal mortality.

PAN receives annual funding from the Ministry of Health of about €900.000. A third of the budget is used for support of the perinatal cooperation groups (PCG's) by the regional teams. About 30% is intended for use and management of the registration systems and for reporting and communication (both including personnel costs). Another third is needed for the PAN office, board and advisory committees.

The objective of this study is to describe the implementation process of this perinatal audit program and to present the results after the first three years of term perinatal audit: perinatal death classification, antepartum high risk selection, identification of substandard (care) factors (SSF), SSF in relation to death and conclusive recommendations for quality improvement in perinatal care.

## Methods

### *Organization and training*

A regional infrastructure with audit support teams has been set up. The teams consist of health care professionals in the 10 tertiary centres for perinatology with a neonatal intensive care unit

(NICU) and obstetric ‘high care’ department facilities. These regional teams were trained by PAN for coordination and support of the audit performance at local (hospital) levels. Subsequently these regional teams trained the audit teams of the local hospitals and the surrounding practices of independent community midwives and general practitioners within their region. PAN cooperated with the IMPACT project that pioneered the introduction of perinatal audit in the Northern region of The Netherlands.<sup>18</sup> PAN offered regular training sessions in organisation of audit, in making narratives, in chairing of the audit meeting and in classification of perinatal mortality. In January 2010 the nationwide Dutch perinatal mortality audit has officially started with the audit of term perinatal mortality as the first topic. Term perinatal mortality was chosen because of the involvement in term pregnancies and deliveries of all professional groups in the obstetric/paediatric/neonatal field. Within The Netherlands community midwives and, on a small scale, general practitioners provide obstetric care (including home birth) to women with antepartum judged low risk profiles. If complications (threaten to) occur the responsibility for obstetric care will be transferred to a medical specialist in a general hospital (secondary care) or tertiary centre. Risk selection during pregnancy and labour in primary or secondary/tertiary care is therefore the essence of the Dutch perinatal care organisation.<sup>19-21</sup>

The Netherlands is divided in 10 perinatal healthcare regions, catchment areas for perinatal high care centres which have NICU facilities. In 2012 there were 90 hospitals with obstetric/paediatric care facilities (97 in 2010 and 93 in 2011). Each hospital and the surrounding community practices of independent midwives and general practitioners are organised in a Perinatal Cooperation Group (PCG). Each PCG is responsible for auditing and registration of the mortality cases in their catchment area.

Representatives of the professionals of the PCG’s analyse the cases in a systematic way, identify substandard care factors (SSF) in delivered care and/or organisation of care, identify the types of professionals involved and classify mortality according to three different systems, i.e. the Wigglesworth /Hey, Modified ReCoDe and Tulip classifications.<sup>22-26</sup> During the audit the professionals relate the degree (non/unlikely, possible, probable, unknown) to whether the SSF was causative for the death. Specific recommendations for improving the quality of care are then formulated. An independent chairperson presides the audit and provides a safe environment. He or she is a perinatal health care professional not practicing in the hospital/PCG where the audit takes place and is often a member of the regional audit team.

Audit with (involved) professionals is a delicate matter and needs careful procedures. The PAN has developed basic rules to enable a safe environment:

- Everything discussed during the audit is confidential. Every participant signs for this.
- Everybody is expert in his own professional field, participants can question professionals in other fields but do not judge them.



- The provided care and cure are assessed by comparing it to formal guidelines or usual care, not by one's own judgment.
- Narratives of the discussed cases that were drawn up before the meeting by members of the PCG are destroyed after the audit.

### *Definitions*

Term perinatal mortality is defined as stillbirth and neonatal mortality during the first four weeks of life in births with gestational ages from 37.0 weeks onwards, including the post term period.<sup>27</sup>

Cases with unknown gestational age were excluded.

A substandard factor (SSF) is present if care that deviated from the safe limits of practice as laid down in national guidelines, local protocols (translation of national guidelines for local use) or normal professional practice.<sup>28</sup> The formal agreed guidelines are accessible at the websites of the professional organisations of the midwives (25 topics), obstetricians (63), paediatricians (29) and general practitioners (3). The agreed referral list for primary and secondary care (VIL, Obstetric Indication List) comprises 125 items<sup>14</sup> (translated in English)<sup>21</sup>. Most guidelines and the referral list items are covering term pregnancies as well. All agreed national guidelines in perinatology and the Obstetric Indication list are also available on the PAN website, arranged by professional organisation and by topic (<http://www.perinataleaudit.nl/bibliotheek/richtlijnen/aandoeningen>).

Antepartum low risk assessment is defined as antepartum judged low risk profile for care during labour and delivery by primary care (community midwife or general practitioner), including delivery at home.<sup>19-21</sup>

### *Registries*

Because the audit focusses on recent cases that require more detailed and up to date information than is present in the national Dutch perinatal registry (PRN), two specific real-time databases were created to support the audit. The first for the registration of perinatal death cases to be audited (PRN-Audit, Perinatal Audit Registry of The Netherlands) and the second for the confidential registration of the audit process and its outcomes (PARS, Perinatal Audit Registry System).

#### **PRN-Audit database**

Term perinatal mortality cases are registered in PRN-Audit by health care professionals. Data are gathered from the medical records and registered with specific details needed to construct the narrative that will be used during the audit. In PRN-Audit supplemental information is included such as professionals involved in the care process, diagnostics, policy decisions, actions (treatments, referrals) and antepartum risk selection with their time frames. The audit narrative, the basic document for the audit meeting, is automatically generated from the PRN-Audit database as an anonymous document.

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**PARS database**

The audit meetings (participants, number of cases discussed) and the outcomes of the audits are registered by the local audit groups in a separate database PARS. Because of privacy restrictions and to create a safe and secure environment for audit participants the PARS database is anonymous; only characteristics such as gestational age (categories) at birth, time (fetal-neonatal) of death and the perinatal death classifications are registered in PARS.

**PRN registry as reference**

The standard national PRN registry contains population-based information on all pregnancies, deliveries from 22 weeks onwards and (re)admissions occurring until 28 days after delivery. The data are collected by different professionals and are linked when year data sets are available which is 1,5 years afterwards. The PRN data is made available to healthcare providers, researchers and policymakers. The completeness of PRN is currently around 96-98% of all births ([www.perinatreg.nl](http://www.perinatreg.nl)).The national PRN database is the reference source for the audit cases in our study.

**Statistical methods**

The study is descriptive. For the comparison of characteristics in the PRN registry with the characteristics in the PRN-Audit/ PARS database, as for trend of time, a chi-squared test is used.

## Results

A total of 943/1102 (86%) cases of term perinatal mortality cases in the period 2010-2012 are registered in the PRN-Audit database and 707 (64%) cases were audited and recorded in the PARS database. Compared to the number of cases in the national perinatal registry PRN, the number of cases that were registered in the PRN-Audit database increased over the years (from 85% in 2010 to 89% in 2012  $p=0.0098$ ) and the registration of cases in PARS showed an increase of 59% in 2010 to 66% in 2012  $p=0.015$  (table 1).

TABLE 1

### ***Number of audit meetings and participants***

Throughout The Netherlands 645 audit meetings took place in 2010-2012 with in total 20,091 participating health care professionals as community (independent) midwives, general practitioners, obstetricians, clinical midwives, nurses, paediatricians, pathologists, registrars, medical students and students in midwifery (with an average of 31 health care professionals per session). The number of participants nearly doubled in 2012 as compared to 2010. Half of the participants was once present, 15% twice and 35% three or more times. Audit participation of all the PCG's reached full coverage in the second year (2011) (table 1).

### ***Substandard factors***

In 53% (376) of the 707 audited cases one or more substandard factors (SSF) were identified (table 2a).

TABLE 2a

A total of 717 SSF's emerged. In 35% of the cases these were related to non-compliance with guidelines or missing appropriate local protocols and in 41 % they implied nonobservance of usual professional care (table 2b).

TABLE 2b

Examples of deviations of guidelines are: no or delayed consultation of the obstetrician in case of suspected fetal growth restriction, no fetal monitoring in case of induction of labour, expectant management in case of non-reassuring cardiotocography, non-optimal application of the guideline for resuscitation of the new born. Examples of deviation of usual care are: no fetal monitoring in case of vaginal blood loss, no consultation or action undertaken in case of decreased fetal movements, no further diagnosis and/or action in case of presumed growth restriction and insufficient documentation in the medical records (medication, diagnostic considerations and policy).

### ***Cause of death***

Autopsy was performed in 38% and pathological examination of the placenta in 77% of the term cases registered for audit. Table 3 gives the results of the death classifications.

TABLE 3

In the Tulip classification 36 % of cases the underlying cause of death is classified as ‘placental’ and sub-classified as placental pathology (31%), followed by umbilical cord complications (28%) and placental bed pathology (28%). Congenital malformation was classified in 19% as the underlying cause of death. In 32% of cases the cause of death is unknown. Using the ReCoDe classifications placenta pathology was the most important clinical condition (24%) with placental insufficiency (n=108) and abruption for 26 cases as main groups. The Wigglesworth/Hey classification shows 62% fetal death and 15% of the pregnancies had a gestational age of ≥41 weeks (Table 3).

**SSF, relation to death and professional involvement**

In 8% (57) of the 707 audited cases the relation of SSF to death was assessed as probable and in 13% (92) as possible. The percentage of cases with one or more SSF remained stable during the years. Of these the cases with non/unlikely relation of SSF’s to death increased from 20% in 2010 to 30% in 2012 (p=0.028) The rate of cases with SSF possibly related to death remained the same during the years, the cases with SSF (very) probably related to death decreased from 10% to 5% (p=0.060) (table 4).

TABLE 4

In total 1269 health care professionals played a role in substandard factors in 376 cases: mean 3.4 professionals per case. Of them 26% were obstetrician, 20% independent community midwife and 12% a clinical midwife. Nurses were involved in 10% of the cases, paediatricians in 7% and registrars in 10% of the cases.

**Antepartum low risk assessment**

For 19% (183) of all registered cases there was antepartum low risk selection for primary care delivery. Antepartum high risk assessment showed a significant increase from 70% to 84% (p=0.001)) (table 5).

TABLE 5

**Recommendations from the audit**

A total of 512 SSF’s were identified in the 376 cases with one or more SSF’s: in 57% (213) of the cases one SSF, in 19% (73) two SSF’s and in 24% (90) three or more SSF’s. This lead to 603 recommendations: in 71% of all indicated SSF’s (512/717) one recommendation is described, and in 6% (41) two and sometimes three recommendations.

Recommendations were in 35 % about the organisation of care as well as for the quality of cooperation inside and outside the hospital between the different professional groups. In 19% the recommendations were for better use of guidelines and following usual care. The

recommendations for guidelines focussed on the development or adjustment of local protocols. In addition recommendations are given for producing local protocols for usual care. A specific frequently pronounced recommendation was the development of a national guideline for reduced fetal movements. In 15% the recommendations are about better documentation of the care process. The advices for better communication (11%) refers to improvement of communication between professionals in community and hospital care. For training and education (17%) recommendations were formulated, for instance training in neonatal resuscitation and in cardiotocography interpretation courses.<sup>26</sup>

On the website of PAN all recommendations are sorted in groups and extensively elaborated <http://www.perinataleaudit.nl/onderwerpen/204/uitwerking-van-aanbevelingen>.

### ***Representativeness of the documented and audited cases***

Distribution of gestational age, congenital malformation and fetal-neonatal death are comparable in PARS and PRN registry (table 6).

Table 6
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The characteristics of the cases from 2010-2012 in PRN-Audit database and in the national PRN database are comparable with regard to the maternal characteristics like parity, maternal age and gestational age except for a lower percentage of women of non-Caucasian ethnicity ( $p=0.04$ ) and of less infants with birth weight  $<2000$  grams ( $p=0.01$ ) (table 6).

Discussion

The Netherlands is the first country with a nationwide perinatal audit that is now systematically performed by all collaborating perinatal health care professionals at the local level. Within two years all hospitals that provide perinatal care with the surrounding and adherent midwifery practices in the country participated in perinatal audit. It proved feasible to audit and register the results of 64% (707) of all cases of term perinatal death, which was a well representative sample of all term perinatal deaths in the Netherlands. Perinatal audit resulted in description of substandard factors (SSF) and many recommendations mostly ready for implementation within the own perinatal cooperation groups .

During the three years audit period term perinatal mortality decreased from 2.3 to 2.0 per 1000 births ( $p<0.00001$ ) (table 1). The percentage of cases with one or more SSF's did not change during these years, but the percentage of cases without or with an unlikely relation of SSF's to death increased ( $p=0.028$ ). Antepartum high risk selection increased from 70% to 84% during the years ( $p=0.001$ ).

Strengths and limitations

Audit by a multidisciplinary team of the health care professionals themselves (internal audit), is a feasible way to increase implementation of the audit results/recommendations in local practice. In the chosen approach in the Netherlands an independent chairperson has proven instrumental to optimize audit performance.<sup>18</sup>

This study concerns perinatal death cases of recent date, the last cases of 2012 were audited in June 2013. Most audits are performed within 3-6 months after death which minimizes the potential loss of knowledge/memory and details of the cases and circumstances that contributed.

Not all term cases of perinatal death are audited. Characteristics of the audited cases however are comparable to all term perinatal death cases in the national registration of the PRN, the registered cases were also comparable except for lesser cases with non-Caucasian ethnicity and lesser cases with birth weight< 2000 gram. This suggests that cases have not been avoided systematically or were lost for discussion in the audit.

Of all audited cases information was insufficient in 11% for SSF assessment. This percentage remained similar during the years and is a point of concern for the next years.

It is unknown whether all audit meetings take place in the most optimal and consistent way. However in our study the percentage of cases with assessed SSF's remained about the same during the years. In our view this fits with a stable audit method.

Knowledge of the outcome can influence the judgment of the care and the relation between the substandard factors and the outcome, especially when the outcome is perinatal death.<sup>29 30</sup>

Although participants could have been too much or too less severe in their judgements the overall nationwide collected output of cases with SSF was quite consistent.

The cause of death according to the Tulip Classification was classified as unknown in 32% of the cases in our study. This high percentage suggests that improvement may be feasible by further training of the audit teams in using the Tulip classification apart from the desirability of more autopsies and placenta biopsies.<sup>25 31</sup>

### ***Comparison with other studies***

There are no other studies with national internal perinatal audit programs, so we can only compare with earlier regional (external) audit studies.

#### ***SSF***

In 36% of the audited cases in our study the audit group did not identify or assess any SSF. This is lower than in earlier regional studies in the Netherlands in 1996-1997 and 2003-2004 with 40-45%.<sup>12 15</sup> A possible explanation is that professionals are more critical about their own delivered care than external audit panels are. Otherwise these studies were performed 10 or even more years ago and in the meantime many guidelines are developed and could be used as reference for SSF.

In 11% of all cases insufficient information was present for SSF assessment. In earlier audit studies in The Netherlands this percentage was 2-4%.<sup>12 15</sup> However, these audits (and narratives) were prepared by one or two dedicated researchers while in the nationwide audit each perinatal cooperation group has to gather all information for the narrative during their daily work.

#### ***SSF and relation to death***

The audit groups found a probable relation of substandard factors to death in 8% (n=57) of all discussed term perinatal death cases. In the LPAS-study, a regional external audit in 2003-2004 in the Netherlands, this was 9%.<sup>15</sup> In earlier studies (external audits) only the combined outcome of possible and probably relation of SSF and death is given. In 25-30% a combined possible or probably relation is found in The Netherlands and even 46% in 10 European regions in 1993-1998 (Euronatal study).<sup>1 11 12 30</sup> These combined percentages were higher than in our recent study (21%) and in the earlier LPAS-study (19%).<sup>15</sup> It is possible that these differences can be (partly) explained by quality of care improvement during the past 20 years. Otherwise it would be desirable to examine whether, compared to external review, our method of internal review with an external chair was more or less likely to identify SSF's with possible/probable relation to the death.

#### ***Classification of perinatal death***

At 36% a placental cause of death in the Tulip classification was the most frequent. This is similar to the results of the LPAS study.<sup>15</sup> In a perinatal death cohort of an university clinic with preterm births included 27% placental cause of death was found.<sup>25</sup>



Comparison of the prevalence of the found causes with other studies is difficult, since other reports on the classification of a cohort of perinatal death do not show the term period separately enough for proper comparison.

*Implications of the study and further research*

A systematic method of perinatal audit has been implemented by all perinatal cooperation groups in The Netherlands. Audits generated many recommendations for quality of care improvements, which are in progress towards implementation. The infrastructure of perinatal audit in The Netherlands had been secured and more topics can be chosen in the future for audit in perinatal care such as preterm mortality or specific morbidity. For the years 2013-2015 the focus is term intrapartum and neonatal death and admission to a neonatal intensive care unit for neonatal asphyxia.

It is assumed that the chance of uptake of actions formulated by local professionals themselves is greater than the uptake of top down imposed advice. In general the implementation of changes in care proves to be difficult.<sup>32</sup> At national level the professional organizations involved now cooperate in the college perinatal care (CPZ), instituted by the Ministry of Health

(<http://www.collegepz.nl/organisatie>). CPZ is coordinating desirable changes in perinatal care.

During the three years studied term perinatal mortality decreased. The percentage of cases with SSF without a relation to death increased while the percentage of cases with SSF and a probable relation to death decreased. Although a direct relationship cannot be proved, the parallel with the synchrony of audit implementation and subsequently declining perinatal mortality in Norway is striking.<sup>9</sup>

Antepartum high risk selection, increased during the years 2010-2012. This can suggest that risk selection became more accurate but this needs further investigation.<sup>33</sup> Some recommendations from the audits have already been implemented such as the need for developing a new national guideline for 'reduced fetal movements'.<sup>34</sup>

**Conclusion**

Within a short time period a systematic method of internal perinatal audit has been implemented by all perinatal cooperation groups in The Netherlands. Audits performed by healthcare professionals themselves generated many recommendations for quality of care improvements which are in progress towards implementation. It is possible that audit contributed to the decrease in term perinatal mortality. With ongoing audits quality of perinatal care can be continuously monitored and instruments for quality of care improvement developed.

These findings can be a stimulus for introduction of nationwide internal perinatal audit in other countries and in other medical disciplines.



**[acknowledgment]**

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The Netherlands Perinatal Registry provided the data of term perinatal mortality.

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**[Contributors]**

Martine Eskes (guarantor), Adja Waelput, Jan Jaap Erwich, Hens Brouwers, Anita Ravelli, Peter Achterberg, Hans Merkus and Hein Bruinse had the core idea for this study. Anita Ravelli and Martine Eskes prepared and analysed the data and/or interpreted the results. Adja Waelput, Martine Eskes and Anita Ravelli wrote the draft of the article. Jan Jaap Erwich, Hens Brouwers, Peter Achterberg, Hans Merkus and Hein Bruinse commented on the manuscript and approved the final version.

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**[Competing interest]**

All authors have completed the Unified Competing Interest form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare: there was no support from any organisation for the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

**[Ethics approval]**

PARS is a complete anonymous registration, no data is traceable to patient and/or health care professional. Therefore no formal ethical approval procedure was waived.

The national perinatal registry of The Netherlands (PRN) provided data from the PRN and PRN-Audit, registered as data request 11.38, 13.45, 13.51, 13.61, 14.09 ([www.perinatereg.nl](http://www.perinatereg.nl)). The PRN has given permission for the analysis of their data.

**[Datasharing]**

Dataset can be requested at the board of Foundation Perinatal Audit in The Netherlands (PAN) [info@perinataleaudit.nl](mailto:info@perinataleaudit.nl).

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**[Transparency declaration]**

Martine Eskes (the manuscript’s guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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**Table1 Term perinatal death cases and audit implementation parameters 2010-2012**

	2010		2011		2012		2010-2012		p-value*
	n	%	n	%	n	%	n	%	
term born children (PRN)	163,276		163,248		160,714		487,238		
term death cases and rate (PRN)									
perinatal	379	0.23%	398	0.24%	325	0.20%	1102	0.23%	<0.00001
fetal	249	0.15%	252	0.15%	217	0.14%	718	0.15%	<0.00001
neonatal	130	0.08%	146	0.09%	108	0.07%	384	0.08%	<0.00001
term death cases in PRN-Audit	324	85%	329	83%	290	89%	943	86%	0.0098
term death cases in PARS	222	59%	272	68%	213	66%	707	64%	0.0147
number PCG's	97		93		90		-		
audit participation of PCG's	94	97%	93	100%	90	100%	-		
meetings	149		244		252		645		
participants	4,291		7,557		8,243		20,091		

PRN= perinatal registry of The Netherlands

PRN-Audit= perinatal audit registry of The Netherlands

PARS= perinatal audit registry system

PCG=perinatal cooperation groups (number decreased by closures of hospitals).

\*chi-square test

**Table 2a Number of substandard factors (SSF) assessed per case of term perinatal death 2010-2012**

SSF per case	n	%
no SSF	252	36%
≥ 1 SSF	376	53%
1	213	30%
2	73	10%
3	43	6%
4	27	4%
≥5	20	3%
insufficient information	79	11%
<b>Total cases</b>	<b>707</b>	<b>100%</b>

**Table 2b Categories of all 717 substandard factors (SSF) in 376 term perinatal death of infants born in 2010-2012**

Category SSF	n	%
non-compliance of guidelines or local protocols missing	250	35%
nonobservance of usual professional care	294	41%
other	173	24%
<b>Total SSF</b>	<b>717*</b>	<b>100%</b>

SSF=substandard factor

\*per case more SSF's can be present

**Table 3 Tulip-classification, modified ReCoDe-classification and Wigglesworth/Hey classification of term perinatal deaths (2010-2012)**

<b>Tulip classification of perinatal mortality</b>							
<b>(underlying cause of death, main groups and placental subgroups)<sup>25</sup></b>							
	n	%					
Congenital anomaly	135	19%					
<b>Placenta</b>	<b>253</b>	<b>36%</b>	→		<b>Placenta</b>		
Infection	32	5%			umbilical cord	70	28%
Other	52	7%			placental bed	71	28%
Unknown	224	32%			development	42	17%
no information	11	2%			parenchyma	31	12%
<b>Total</b>	<b>707</b>	<b>100%</b>			localisation	6	2%
					NOS	33	13%
					<b>Total</b>	<b>253</b>	<b>100%</b>

  

<b>Modified ReCoDe classification, most relevant condition at death (main groups and placental subgroups)<sup>23 24</sup></b>							
	n	%					
Fetus group	85	13%					
Neonate	129	20%					
Umbilical cord	60	9%					
<b>Placenta</b>	<b>155</b>	<b>24%</b>	→		<b>Placenta</b>		
amniotic fluid	4	1%			abruptio	26	17%
Uterus	6	1%			praevia	2	1%
Mother	26	4%			vasa praevia	9	6%
Intrapartum	28	4%			placental insufficiency	108	70%
Trauma	2	0%			other	10	6%
Unclassified	130	20%			<b>total</b>	<b>155</b>	<b>100%</b>
Unknown	31	5%					
<b>Total</b>	<b>656</b>	<b>100%</b>					
not eligible	51*						

  

<b>Wigglesworth/Hey classification<sup>22</sup></b>							
	fetal		neonatal		unknown period		total
<b>Delivery at</b>	n	%	n	%	n	%	n
37-40.6 wks	373	62%	217	36%	8	1%	598
≥ 41 wks	67	61%	42	39%	-	-	109
<b>total</b>	<b>440</b>	<b>62%</b>	<b>259</b>	<b>37%</b>	<b>8</b>	<b>1%</b>	<b>707</b>

\* =during the first year missing data because of registration limitation for ReCoDe most relevant condition

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**Table 4 Substandard factors (SSF) and relation to death in term perinatal death in 2010-2012**

relation to death\$	2010		2011		2012		2010-2012		p-value*
	n	%	n	%	n	%	n	%	
cases with SSF	116	52%	147	54%	113	53%	376	53%	0.92
none/unlikely	45	20%	75	28%	63	30%	183	26%	<b>0.028</b>
possibly	28	13%	32	12%	32	15%	92	13%	0.47
(very) probably	23	10%	24	9%	10	5%	57	8%	0.060
unknown	20	9%	16	6%	8	4%	44	6%	0.053
cases without SSF	75	34%	97	36%	80	38%	252	36%	0.71
cases with insufficient information	31	14%	28	10%	20	9%	79	11%	0.26
Total cases	222	100%	272	100%	213	100%	707	100%	
SSF=substandard factor									
* Chi-square test									

**Table 5 Level of care at start of labour, period of death and year of birth in term perinatal mortality**

Level of care at start of labour	perinatal death		fetal death		neonatal death	
	n	%	n	%	n	%
primary care	183	19%	101	11%	82	9%
secondary/tertiary care	730	77%	508	54%	222	24%
unknown	30	3%	4	0%	26	3%
Total	943	100%	613	65%	330	35%

  

	primary care		secondary/tertiary care		unknown		total
year	n	%	n	%	n	%	n
2010	68	21%	227	70%	29	9%	324
2011	69	21%	259	79%	1	0%	329
2012	46	16%	244	84%	0	0%	290
2010-2012	183	19%	730	77%	30	3%	943
p-value*	p=0.19		p=0.001				

\*Chi-square test

**Table 6 Characteristics of term perinatal mortality in PARS and PRN-Audit versus PRN 2010-2012**

Characteristics	PARS		PRN		p-value*
	n	%	n	%	
gestational age (weeks)					0.91
37.0-40.6	598	85%	930	84%	
≥41.0	109	15%	172	16%	
congenital malformations	135	19%	238	22%	0.20
moment of death					0.40
fetal	440	62%	718	65%	
neonatal	259	37%	384	35%	
unknown period	8	1%			
<b>Total</b>	<b>707</b>	<b>100%</b>	<b>1102</b>	<b>100%</b>	

  

Characteristics	PRN-Audit		PRN		p-value*
	n	%	n	%	
parity 0	450	48%	536	49%	0.68
age mother (years)					
<20	6	1%	11	1%	0.37
≥35	243	26%	292	26%	0.71
non-Caucasian ethnicity	185	20%	257	23%	<b>0.04</b>
congenital malformation	194	21%	238	22%	0.57
period of death					0.94
fetal	613	65%	718	65%	
neonatal	330	35%	384	35%	
birth weight (grams)					
<2000	30	3%	60	5%	<b>0.01</b>
2000-2499	85	9%	98	9%	0.92
≥4500	22	2%	22	2%	0.60
gestational age (weeks)					
37.0-39.6	579	61%	707	64%	0.20
40.0-41.6	341	36%	371	34%	0.12
≥42.0	23	2%	24	2%	0.69
<b>Total</b>	<b>943</b>		<b>1102</b>		

PRN= perinatal registry of The Netherlands  
PRN-Audit= perinatal audit registry of The Netherlands  
PARS= perinatal audit registry system  
\* Chi-square test



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# Term perinatal mortality audit in The Netherlands 2010-2012: a population based cohort study

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**ABSTRACT**

**Objective**

To assess the implementation and first results of term perinatal internal audit by a standardised method.

**Design**

Cohort study.

**Setting**

All 90 Dutch hospitals with obstetric-paediatric departments linked to community practices of midwives, general practitioners in their attachment areas, organised in perinatal cooperation groups (PCG) participated in the study.

**Population**

The population existed of 943 registered cases of term perinatal death occurring in 2010-2012 with detailed information, including 707 cases with completed audit results.

**Main outcome measures**

Participation in audit, perinatal death classification, identification of substandard factors (SSF), SSF in relation to death, conclusive recommendations for quality improvement in perinatal care and antepartum risk selection at start of labour.

**Results**

After the introduction of perinatal audit in 2010, all PCG's participated. They organised 645 audit sessions, with an average of 31 health care professionals per session.

Of all 1102 term perinatal deaths (2.3 per 1000) data were registered for 86% (943) and standardized anonymized audit results for 64% (707).

In 53% of the cases at least one SSF was identified. Non-compliance to guidelines (35%) and nonobservance of usual care (41%) were the most frequent SSF.

There was a probable relation between the SSF and perinatal death for 8% of all cases. This declined over the years: from 10% (n=23) in 2010 to 5% (n=10) in 2012 (p=0.060). Simultaneously term perinatal mortality decreased from 2.3 to 2.0 per 1000 births (p<0.00001).

Possibilities for improvement were identified in the organisation of care (35%), guidelines or usual care (19%) and in documentation (15%).

More pregnancies were antepartum selected as high risk, 70% in 2010 and 84% in 2012 (p=0.001).

**Conclusions**

Perinatal audit is nationwide implemented in all obstetrical units in The Netherlands in a short time period. It is possible that audit contributed to the decrease in term perinatal mortality.

## Strengths and limitations of this study

- The Netherlands is the first country in which all collaborating perinatal health care professionals nationwide participate in an internal perinatal audit systematically performed at the local level.
- Within two years all hospitals in the country providing obstetric/paediatric care with their surrounding midwifery practices participated in perinatal audit.
- Perinatal audit resulted in description of substandard factors (SSF), relation to death and the formulation of many recommendations mostly ready for implementation.
- Not all term perinatal deaths are audited. Characteristics of the audited cases are comparable to all term perinatal mortality cases in the national registration.
- Of all audited cases information was insufficient in 11% for substandard factor assessment. This is a major point of attention for the next years.

Introduction

Perinatal mortality is an important indicator of the quality of perinatal care.<sup>1</sup> In 2000 The Netherlands had the highest perinatal mortality rate ~~as when~~ compared to a large group of European countries.<sup>2,3</sup> Although perinatal mortality in The Netherlands has ~~in later years~~ decreased ~~in later years~~, in 2010, the ranking relative to other European countries showed only a modest improvement. ~~Research suggests that improving (preventive) care can lead to perinatal health gains.~~<sup>4,5</sup>

These ~~se~~ outcomes of the international benchmarks were an important incentive for Dutch politicians and professionals in the field of perinatal care to investigate the determinants of perinatal mortality including assessment of the quality of care. One of ~~the most suitable procedures possible~~ interventions in this regard is the introduction of perinatal audit, a critical and systematic analysis of the quality of perinatal care.<sup>6</sup> ~~Earlier t~~The introduction of perinatal audit in Norway has been an important factor in improving the quality of perinatal care and preceded a decline of perinatal mortality in Norway.<sup>7-9</sup>

In the Netherlands, perinatal audit studies were undertaken in the eighties of the past century. These audits were local or regional one-time studies.<sup>10-12</sup> More recently ~~and with strong support from the government~~ the professional organisations involved have jointly prepared the introduction of a nationwide perinatal mortality audit program that would become a standard part of perinatal care.<sup>13-17</sup> The Foundation Perinatal Audit in the Netherlands (PAN) was set up by the professional organisations of midwives, general practitioners, obstetricians, paediatricians, and pathologists ([www.perinataleaudit.nl](http://www.perinataleaudit.nl)). The first nationwide Dutch perinatal mortality audit has started in the period 2010-2012 with the focus on audit of term perinatal mortality.

PAN receives annual funding from the Ministry of Health of about €900.000. A third of the budget is used for support of the perinatal cooperation groups (PCG's) by the regional teams. About 30% is intended for use and management of the registration systems and for reporting and communication (both including personnel costs). Another third is needed for the PAN office, board and advisory committees.

The objective of this study is to describe the implementation process of this perinatal audit program and to present the results after the first three years of term perinatal audit: perinatal death classification, antepartum ~~low-high~~ risk selection ~~(for supervision of the first line at start of labour)~~, identification of substandard (care) factors (SSF), SSF in relation to death and conclusive recommendations for quality improvement in perinatal care.

Methods

### Organization and training

A regional infrastructure with audit support teams has been set up. The teams consist of health care professionals in the 10 tertiary centres for perinatology with a neonatal intensive care unit (NICU) and obstetric 'high care' department facilities. These regional teams were trained by PAN for coordination and support of the audit performance at local (hospital) levels. Subsequently these regional teams trained the audit teams of the local hospitals and the surrounding practices of independent community midwives and general practitioners (~~Perinatal Cooperation Groups~~) within their region. PAN cooperated with the IMPACT project that pioneered the introduction of perinatal audit in the Northern region of The Netherlands.<sup>18</sup> PAN offered regular training sessions in organisation of audit, in making narratives, in chairing of the audit meeting and in classification of perinatal mortality.

In January 2010 the nationwide Dutch perinatal mortality audit has officially started with the audit of term perinatal mortality as the first topic. Term perinatal mortality was chosen because of the involvement in term pregnancies and deliveries of all professional groups in the obstetric/paediatric/neonatal field. Within The Netherlands community midwives and, on a small scale, general practitioners provide obstetric care (including home birth) to women with antepartum judged low risk profiles. If complications (threaten to) occur the responsibility for obstetric care will be transferred to a medical specialist in a general hospital (secondary care) or tertiary centre. Risk selection during pregnancy and labour in primary or secondary/tertiary care is therefore the essence of the Dutch perinatal care organisation.<sup>19-21</sup>

The Netherlands is divided in 10 perinatal healthcare regions, catchment areas for perinatal high care centres which have NICU facilities. In 2012 there were 90 hospitals with obstetric/paediatric care facilities (97 in 2010 and 93 in 2011). Each hospital and the surrounding community practices of independent midwives and general practitioners are organised in a Perinatal Cooperation Group (PCG). Each PCG is responsible for auditing and registration of the mortality cases in their catchment area.

Representatives of the professionals of the PCG's analyse the cases in a systematic way, identify substandard care factors (SSF) in delivered care and/or organisation of care, identify the types of professionals involved and classify mortality according to three different systems, i.e. the Wigglesworth /Hey, Modified ReCoDe and Tulip classifications.<sup>22-26</sup> During the audit the professionals relate the degree (non/unlikely, possible, probable, unknown) to whether the SSF was causative for the death. Specific recommendations for improving the quality of care are then formulated. An independent chairperson presides the audit and provides a safe environment. He or she is a perinatal health care professional not practicing in the hospital/PCG where the audit takes place and is often a member of the regional audit team.

Audit with (involved) professionals is a delicate matter and needs careful procedures. The PAN has developed basic rules to enable a safe environment:



- Everything discussed during the audit is confidential. Every participant signs for this.
- Everybody is expert in his own professional field, participants can question professionals in other fields but do not judge them.
- The provided care and cure are assessed by comparing it to formal guidelines or usual care, not by one's own judgment.
- Narratives of the discussed cases that were drawn up before the meeting by members of the PCG are destroyed after the audit.

*Definitions*

Term perinatal mortality is defined as stillbirth and neonatal mortality during the first four weeks of life in births with gestational ages from 37.0 weeks onwards, including the post term period.<sup>27</sup>

Cases with unknown gestational age were excluded.

A substandard factor (SSF) is ~~defined as a care management problem involving~~present if care that deviated from the safe limits of practice as laid down in national guidelines, ~~standards, local~~ protocols (translation of national guidelines for local use) or normal professional practice.<sup>28</sup> The formal agreed guidelines are accessible at the websites of the professional organisations of the midwives (25 topics), obstetricians (63), paediatricians (29) and general practitioners (3). The agreed referral list for primary and secondary care (VIL, Obstetric Indication List) comprises 125 items<sup>14</sup> (translated in English)<sup>21</sup>. Most guidelines and the referral list items are covering term pregnancies as well. All agreed national guidelines in perinatology and the Obstetric Indication list are also available on the PAN website, arranged by professional organisation and by topic (<http://www.perinataleaudit.nl/bibliotheek/richtlijnen/aandoeningen>).

Antepartum low risk assessment is defined as antepartum judged low risk profile for care during labour and delivery by primary care (community midwife or general practitioner), including delivery at home.<sup>19-21</sup>

*Registries*

Because the audit focusses on recent cases that require more detailed and up to date information than is present in the national Dutch perinatal registry (PRN), two specific real-time databases were created to support the audit. The first for the registration of perinatal mortality-death cases to be audited (PRN-Audit, Perinatal Audit Registry of The Netherlands) and the second for the confidential registration of the audit process and its outcomes (PARS, Perinatal Audit Registry System).

**PRN-Audit database**

Term perinatal mortality cases are registered in PRN-Audit by health care professionals. Data are gathered from the medical records and registered with specific details needed to construct the



narrative that will be used during the audit. In PRN-Audit supplemental information is included such as professionals involved in the care process, diagnostics, policy decisions, actions (treatments, referrals) and antepartum ~~low-risk selection (for supervision of the first line at start of labour)~~ with their time frames. The audit narrative, the basic document for the audit meeting, is automatically generated from the PRN-Audit database as an anonymous document.

### PARS database

The audit meetings (participants, number of cases discussed) and the outcomes of the audits are registered by the local audit groups in a separate database PARS.

Because of privacy restrictions and to create a safe and secure environment for audit participants the PARS database is anonymous; only characteristics such as gestational age (categories) at birth, time (fetal-neonatal) of death (~~Wigglesworth classification~~) and the underlying cause of perinatal death classifications ~~death category (Tulip classification)~~ are registered in PARS.

### PRN registry as reference

The standard national PRN registry contains population-based information on all pregnancies, deliveries from 22 weeks onwards and (re)admissions occurring until 28 days after delivery ([www.perinatreg.nl](http://www.perinatreg.nl)). The data are collected by different professionals and are linked when year data sets are available which is 1,5 years afterwards. The PRN data is made available to healthcare providers, and made available in reports, to researchers and policymakers.<sup>20,28</sup> The completeness of PRN is currently around 96-98% of all births. ([www.perinatreg.nl](http://www.perinatreg.nl)). ~~This The~~ national PRN database is the reference source for the audit cases in our study.

### Statistical methods

The study is descriptive. ~~In For the~~ comparison of characteristics in the PRN registry with the characteristics in the PRN-Audit/ PARS database, as for trend of time, a chi-squared test is used.

### Ethical approval

~~Anonymous registry data are used, no ethical approval is needed.~~

~~The Dutch perinatal registry has given permission for the analysis of their data.~~

Results

A total of 943/1102 (86%) cases of term perinatal mortality cases in the period 2010-2012 are registered in the PRN-Audit database and 707 (64%) cases were audited and recorded in the PARS database. Compared to the number of cases in the national perinatal registry PRN, the number of cases that were registered in the PRN-Audit database increased over the years (from 85% in 2010 to 89% in 2012  $p=0.0098$ ) and the registration of cases in PARS showed an increase of 59% in 2010 to 66% in 2012  $p=0.015$  (table 1).

TABLE 1

**Number of audit meetings and participation in audit of professionals**

Throughout The Netherlands 645 audit meetings took place in 2010-2012 with in total 20,091 participating health care professionals as community (independent) midwives, general practitioners, obstetricians, clinical midwives, nurses, paediatricians, pathologists, registrars, medical students and students in midwifery (with an average of 31 health care professionals per session). The number of participants nearly doubled in 2012 as compared to 2010. Half of the participants was once present, 15% twice and 35% three or more times. Audit participation of all the perinatal cooperation groups PCG's reached full coverage in the second year (2011) (table 1).

**Substandard factors**

In 53% (376) of the 707 audited cases one or more substandard factors (SSF) were identified (table 2a).

TABLE 2a

A total of 717 SSF's emerged. In 35% of the cases these were related to not following non-compliance with guidelines (without motivation) or missing appropriate local protocols and in 41 % they implied a deviation nonobservance of usual professional care (table 2b).

TABLE 2b

Examples of deviations of guidelines are: no or delayed consultation of the obstetrician in case of suspected fetal growth restriction, no fetal monitoring in case of induction of labour, expectant policy management in case of non-reassuring cardiotocography, non-optimal following application of the guideline for resuscitation of the new born. Examples of deviation of usual care are: no fetal monitoring in case of vaginal blood loss, no consultation or action undertaken in case of less decreased fetal movements, no further diagnosis and/or action in case of presumed growth restriction and insufficient documentation in the medical records (medication, diagnostic considerations and policy).

**Cause of death**

Autopsy was performed in 38% and pathological examination of the placenta in 77% of the term cases registered for audit. Table 3 gives the ~~underlying cause of death using the Tulip classification results of the death classifications.~~

**TABLE 3**

In ~~the Tulip classification~~ 36 % of cases the ~~underlying~~ cause of death is classified as 'placental' and sub-classified as placental pathology (31%), followed by umbilical cord complications (28%) and placental bed pathology (28%). Congenital malformation was classified in 19% as the underlying cause of death. In 32% of cases the cause of death is unknown. ~~Using the ReCoDe classifications placenta pathology was the most important clinical condition (24%) with placental insufficiency (n=108) and abruption for 26 cases as main groups. The Wigglesworth/Hey classification shows 62% fetal death and 15% of the pregnancies had a gestational age of ≥41 weeks (Table 3).~~

### **SSF, relation to death and professional involvement**

In 8% (57) of the 707 audited cases the relation of SSF to death was ~~ascertained-assessed~~ as probable and in 13% (92) as possible. ~~The percentage of cases with one or more SSF remained stable during the years. Of these t~~The ~~cases with probable-non/unlikely~~ relation of SSF's to death ~~halved-increased~~ from ~~2040~~% in 2010 to ~~530~~% in 2012 ( $p=0.028$ ) (table 4). ~~The rate of cases with SSF possibly related to death remained the same during the years, the cases with SSF (very) probably related to death decreased from 10% to 5% ( $p=0.060$ ) (table 4).~~

**TABLE 4**

In total 1269 health care professionals played a role in substandard factors in 376 cases: mean 3.4 professionals per case. Of them 26% were obstetrician, 20% independent community midwife and 12% a clinical midwife. Nurses were involved in 10% of the cases, paediatricians in 7% and registrars in 10% of the cases.

### **Antepartum low risk assessment**

For 19% (183) of all registered cases there was antepartum low risk ~~assessment, thus primary care supervision at start of labour took place selection for primary care delivery.~~ Antepartum ~~low~~ ~~high~~ risk assessment showed a ~~significant decrease-increase by 24% in 2012 compared to 2010~~ (from ~~21.70~~% to ~~16.84~~%-respectively ( $p=0.001$ )) (table 5).

**TABLE 5**

### **Recommendations from the audit**

~~A total of 512 SSF's were identified in the 376 cases with one or more SSF's: In total 603 recommendations are given. in 57% (213) of the cases one SSF, in 19% (73) two SSF's and in 24% (90) three or more SSF's. This lead to 603 recommendations: in 71% of all indicated SSF's~~

(512/717) one recommendation is described, and in 6% (41) two and sometimes three recommendations. Recommendations were in 35 % ~~these were~~ about the organisation of care as well as for the quality of cooperation inside and outside the hospital between the different professional groups. In 19% the recommendations were for better use of guidelines and following usual care. The recommendations for guidelines focussed on the development or adjustment of local protocols. In addition recommendations are given for producing local protocols for usual care. A specific frequently pronounced recommendation was the development of a national guideline for reduced foetal movements. In 15% ~~of cases~~ the recommendations are about better documentation of the care process. The advices for better communication (11%) refers to improvement of communication between professionals in community and hospital care. For training and education (17%) recommendations were formulated, for instance training in neonatal resuscitation ~~training~~ and in cardiotocography interpretation courses.<sup>26</sup> On the website of PAN all recommendations are sorted in groups and extensively elaborated <http://www.perinataleaudit.nl/onderwerpen/204/uitwerking-van-aanbevelingen>.

***Representativeness of the documented and audited cases***

Distribution of gestational age, congenital malformation and foetal-neonatal death are comparable in PARS and PRN registry (table 6a).

**Table 6**

The characteristics of the cases from 2010-2012 in PRN-Audit database and in the national PRN database are comparable with regard to the ~~mothers-maternal~~ characteristics like parity, maternal age and gestational age except for a lower percentage of women ~~with-of~~ non-Caucasian ethnicity (p=0.04) and of ~~lower-less infants with~~ birth weight <2000 grams (p=0.01) (table 6b).

## Discussion

The Netherlands is the first country with a nationwide perinatal audit that is now systematically performed by all collaborating perinatal health care professionals at the local level. Within two years all hospitals that provide ~~obstetric/paediatric~~perinatal care with the surrounding and adherent midwifery practices in the country participated in perinatal audit. It proved feasible to audit and register the results of 64% (707) of all cases of term perinatal ~~death~~mortality, which ~~proved to be~~was a well representative sample of all term perinatal ~~mortality cases~~deaths in the Netherlands. Perinatal audit resulted in description of substandard factors (SSF) and ~~the formulation of~~ many recommendations mostly ready for implementation within the own perinatal cooperation groups .

During the three years audit period term perinatal mortality decreased ~~with 13%~~ from 2.3 to 2.0 per 1000 births ( $p<0.00001$ ) (table 1). The ~~percentage of cases with one or more SSF's did not change during these years, but the percentage of cases without or with an probable unlikely~~ relation of SSF's to death ~~halved~~increased ( $p=0.028$ ) ~~from 10% of all cases in 2010 to 5% in 2012~~. Antepartum high risk selection ~~for primary care supervision at start of labour showed improvement~~increased ~~with decrease~~ from 2170% to 4684% during the years ( $p=0.001$ ).

### Strengths and limitations

Audit by a multidisciplinary team of the health care professionals themselves (internal audit), is a feasible way to increase implementation of the audit results/recommendations in local practice. In the chosen approach in the Netherlands an independent chairperson has proven instrumental to optimize audit performance.<sup>18</sup>

This study concerns perinatal ~~mortality~~death cases of recent date, the last cases of 2012 were audited in June 2013. Most audits are performed within 3-6 months after death which minimizes the potential loss of knowledge/memory and details of the cases and circumstances that contributed.

Not all term cases of perinatal ~~mortality~~death are audited. Characteristics of the audited cases ~~however~~ are comparable to all term perinatal ~~mortality~~death cases in the national registration of the PRN, the registered cases were also comparable except for lesser cases with non-Caucasian ethnicity and lesser cases with birth weight < 2000 gram. This suggests that cases have not been avoided systematically or were lost for discussion in the audit.

Of all audited cases information was insufficient in 11% for SSF assessment. This percentage ~~showed a substantial decrease~~remained similar during the years and is a point of concern for the next years.

It is unknown whether all audit meetings take place in the most optimal and consistent way. ~~PAN offered therefore regular training sessions in organisation of audit, in making narratives, in chairing of the audit meeting and in classification of perinatal mortality.~~

However in our study the percentage of cases with assessed SSF's remained about the same during the years. In our view this fits with a stable audit method.  
Knowledge of the outcome can influence the judgment of the care and the relation between the substandard factors and the outcome, especially when the outcome is perinatal death.<sup>29 30</sup>  
Although participants could have been too much or too less severe in their judgements the overall nationwide collected output of cases with SSF was quite consistent.

The cause of death according to the Tulip Classification was classified as unknown in 32% of the cases in our study. This high percentage suggests that improvement may be ~~possible~~/feasible by further training of the audit teams in using the Tulip classification ~~besides apart from~~ the desirability of more autopsies and placenta biopsies.<sup>25 31</sup>

~~Knowledge of the outcome can influence the judgment of the care and the relation between the substandard factors and the outcome, especially when the outcome is perinatal death.~~

**Comparison with other studies**

There are no other studies with national internal perinatal audit programs, so we can only compare with earlier regional (external) audit studies, ~~most of them performed in The Netherlands.~~

**SSF**

~~The outcomes of the assessment of SSF's in this study are comparable with the outcomes of previous regional studies in The Netherlands<sup>10-12</sup>, European regions<sup>1</sup> and a regional study in Norway.<sup>9</sup>~~

In 36% of the audited cases in our study the audit group did not identify or assess any SSF. This is lower than in earlier regional studies in the Netherlands in 1996-1997 and 2003-2004 with 40-45%.<sup>12 15</sup> A possible explanation is that professionals are more critical about their own delivered care than external audit panels are.<sup>30</sup> Otherwise these studies were performed 10 or even more years ago and in the meantime many guidelines are developed and could be used as reference for SSF.

In 11% of all cases insufficient information was present for SSF assessment. In earlier audit studies in The Netherlands this percentage was 2-4%.<sup>12 15</sup> However, these audits (and narratives) were prepared by one or two dedicated researchers while in the nationwide audit each perinatal cooperation group has to gather all information for the narrative during their daily work.

**SSF and relation to death**

The audit groups found a probable~~ey~~ relation of substandard factors to death in 8% (n=57) of all discussed term perinatal ~~mortality-death~~ cases. In the LPAS-study, a regional external audit ~~study~~ in 2003-2004 in the Netherlands, this was 9%.<sup>15</sup> In earlier studies (external audits) only the combined outcome of possible and ~~likely-probably~~ relation of SSF and death is given. In 25-30% a



combined possible or likely-probably relation is found ~~between SSF and perinatal mortality~~ in The Netherlands and even 46% in 10 European regions in 1993-1998 (Euronatal study).<sup>1 11 12 30</sup> These combined percentages were higher than in our recent study (21%) and in the earlier LPAS-study (19%).<sup>15</sup> ~~In the Euronatal study the percentage of cases with such suboptimal care factors was significantly lower in the Finnish (32%) and Swedish (36%) regions compared with the remaining regions. It is possible that these differences can be (partly) explained by quality of care improvement during the past 20 years. Otherwise it would be desirable to examine whether, compared to external review, our method of internal review with an external chair was more or less likely to identify SSF's with possible/probable relation to the death.~~

### Classification of perinatal death

At 36% a placental cause of death in the Tulip classification was the most frequent. This is similar to the results of the LPAS study.<sup>15</sup> In a perinatal death cohort of an university clinic with preterm births included 27% placental cause of death was found.<sup>25</sup> Comparison of the prevalence of the found causes with other studies is difficult, since other reports on the classification of a cohort of perinatal death do not show the term period separately enough for proper comparison.

### *Implications of the study and further research*

A systematic method of perinatal audit has been implemented by all perinatal cooperation groups in The Netherlands. Audits generated many recommendations for quality of care improvements, which are in progress towards implementation. The ~~foundation-infrastructure of~~ perinatal audit ~~is laid~~ in The Netherlands had been secured and more topics can be chosen in the future for audit in perinatal care such as preterm mortality or specific morbidity. ~~(for instance severe neonatal asphyxia or severe maternal morbidity).~~ For the years 2013-2015 the focus is term intrapartum and neonatal death and admission to a neonatal intensive care unit for neonatal asphyxia.

It is assumed that the chance of uptake of actions formulated by local professionals themselves is greater than the uptake of top down imposed advice. In general the implementation of changes in care proves to be difficult.<sup>32</sup> At national level the professional organizations involved now cooperate in the college perinatal care (CPZ), instituted by the Ministry of Health (<http://www.collegepz.nl/organisatie>). CPZ is coordinating desirable changes in perinatal care.

During the three years studied term perinatal mortality decreased. The percentage of cases with SSF without a probable relation ~~with SSF to perinatal death decreased-increased and risk selection improved~~ while the percentage of cases with SSF and a probable relation to death decreased.

Although a direct relationship cannot be proved, the parallel with the synchrony of audit implementation and subsequently declining perinatal mortality in Norway is striking.<sup>9</sup>

~~Term perinatal mortality cases who were antepartum selected as low risk~~Antepartum high risk selection (with start of labour occurring under primary care supervision), decreased by a quarter increased during the years 2010-2012. This can suggest that risk selection became more accurate ~~and but~~ this needs further investigation.<sup>33</sup>

Some recommendations from the audits have already been implemented such as the need for developing a new national guideline for 'reduced fetal movements'.<sup>34</sup>

**Conclusion**

Within a short time period a systematic method of internal perinatal audit has been implemented by all perinatal cooperation groups in The Netherlands. Audits performed by healthcare professionals themselves generated many recommendations for quality of care improvements which are in progress towards implementation. It is possible that audit contributed to the decrease ~~of in~~ term perinatal mortality. With ongoing audits quality of perinatal care can be continuously monitored and instruments for quality of care improvement developed.

These findings can be a stimulus for introduction of nationwide internal perinatal audit in other countries and in other medical disciplines.

[acknowledgment]

This study was not possible without the very committed Dutch perinatal professionals: midwives, obstetricians, pediatricians/neonatologists, nurses, pathologists and others that participated in the audits.

The Netherlands Perinatal Registry provided the ~~reference~~ data of term perinatal mortality. The perinatal audit as program is funded by The Ministry of Health (VWS).

[Contributors]

Martine Eskes (guarantor), Adja Waelput, ~~Martine Eskes (guarantor)~~, Jan Jaap Erwich, Hens Brouwers, Anita Ravelli, Peter Achterberg, Hans Merkus and Hein Bruinse had the core idea for this study. Anita Ravelli and Martine Eskes prepared and analysed the data and/or interpreted the results. Adja Waelput, Martine Eskes and Anita Ravelli wrote the draft of the article. Jan Jaap Erwich, Hens Brouwers, Peter Achterberg, Hans Merkus and Hein Bruinse commented on the manuscript and approved the final version.

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[Competing interest]



All authors have completed the Unified Competing Interest form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare: there was no support from any organisation for the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

[~~Ethical~~ Ethics approval]

~~PARS is a complete anonymous registration, no data is traceable to patient and/or health care professional. Therefore no formal ethical approval procedure was waived.~~

~~The national perinatal registry of The Netherlands (PRN) provided data from the PRN and PRN-Audit, registered as data request 11.38, 13.45, 13.51, 13.61, 14.09 ([www.perinatereg.nl](http://www.perinatereg.nl)).~~

~~Anonymous registry data are used, no ethical approval is needed.~~

The ~~Dutch perinatal registry~~ PRN has given permission for the analysis of their data.

[Datasharing]

Dataset can be requested at the board of Foundation Perinatal Audit in ~~I~~the Netherlands (PAN) [info@perinataleaudit.nl](mailto:info@perinataleaudit.nl). ~~Consent was not obtained, data are anonymized.~~

[Transparency declaration]

Martine Eskes (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Table1 Term perinatal ~~mortality-death~~ cases and audit implementation parameters 2010-2012

	2010		2011		2012		2010-2012		<u>p-value*</u>
	n	%	n	%	n	%	n	%	
term born children (PRN)	163,276		163,248		160,714		487,238		
term <del>mortality-death</del> cases and rate (PRN)	<u>379</u>	<u>0.23%</u>	<u>398</u>	<u>0.24%</u>	<u>325</u>	<u>0.20%</u>	<u>1102</u>	<u>0.23%</u>	
<u>perinatal</u>	<u>379</u>	<u>0.23%</u>	<u>398</u>	<u>0.24%</u>	<u>325</u>	<u>0.20%</u>	<u>1102</u>	<u>0.23%</u>	<u>&lt;0.00001</u>
fetal	249	0.15%	252	0.15%	217	0.14%	718	0.15%	<u>&lt;0.00001</u>
neonatal	130	0.08%	146	0.09%	108	0.07%	384	0.08%	<u>&lt;0.00001</u>
term <del>mortality-death</del> cases in PRN-Audit	324	85%	329	83%	290	89%	943	86%	<u>0.0098</u>
term <del>mortality-death</del> cases in PARS	222	59%	272	68%	213	66%	707	64%	<u>0.0147</u>
<del>perinatal-cooperation</del> <del>groupsnumber-(PCG's)</del>	97		93		90		-		
audit participation of PCG's	94	97%	93	100%	90	100%	-		
meetings	149		244		252		645		
participants	4,291		7,557		8,243		20,091		

PRN= perinatal registry of The Netherlands

PRN-Audit= perinatal audit registry of The Netherlands

PARS= perinatal audit registry system

PCG=perinatal cooperation groups (number decreased by closures of hospitals).

\*chi-square test

**Table 2a** Number of substandard factors (SSF) assessed per case in term  
in perinatal mortality death 2010-2012

<u>SSF per case</u>	n	%
no SSF	252	36%
≥ 1 SSF	376	53%
<u>1</u>	<u>213</u>	<u>30%</u>
<u>2</u>	<u>73</u>	<u>10%</u>
<u>3</u>	<u>43</u>	<u>6%</u>
<u>4</u>	<u>27</u>	<u>4%</u>
<u>≥5</u>	<u>20</u>	<u>3%</u>
insufficient information	79	11%
<b>Total cases</b>	<b>707</b>	<b>100%</b>

**Table 2b** Categories of all 717 substandard factors (SSF) in 376 term perinatal mortality  
death of infants born in 2010-2012

Category SSF	n	%
<u>non-compliance of guidelines or local</u> <u>protocols missing</u>	250	35%
<u>nonobservance of</u> usual <u>professional</u> care	294	41%
other	173	24%
<b>Total SSF</b>	<b>717*</b>	<b>100%</b>

SSF=substandard factor

\*per case more SSF's can be present

**Table 3 Tulip-classification, modified ReCoDe-classification and Wigglesworth/Hey classification of term perinatal mortality deathscases by main group and placental subgroup (2010-2012)**

Tulip classification of perinatal mortality (underlying cause of death, main groups and placental subgroups) <sup>25</sup>					
	n	%			
Congenital anomaly	135	19%			
<b>Placenta</b>	<b>253</b>	<b>36%</b>	⇒	<b>Placenta</b>	
Infection	32	5%		umbilical cord	70 28%
Other	52	7%		placental bed	71 28%
Unknown	224	32%		development	42 17%
no information	11	2%		parenchyma	31 12%
<b>Total</b>	<b>707</b>	<b>100%</b>		localisation	6 2%-
				NOS	33 13%
				<b>Total</b>	<b>253 100%</b>

**Modified ReCoDe classification, most relevant condition at death (main groups and placental subgroups) <sup>23 24</sup>**

	<u>n</u>	<u>%</u>			
<u>Fetus group</u>	<u>85</u>	<u>13%</u>			
<u>Neonate</u>	<u>129</u>	<u>20%</u>			
<u>Umbilical cord</u>	<u>60</u>	<u>9%</u>			
<b><u>Placenta</u></b>	<b><u>155</u></b>	<b><u>24%</u></b>	→	<b><u>Placenta</u></b>	
<u>amniotic fluid</u>	<u>4</u>	<u>1%</u>		abruptio	26 17%
<u>Uterus</u>	<u>6</u>	<u>1%</u>		praevia	2 1%
<u>Mother</u>	<u>26</u>	<u>4%</u>		vasa praevia	9 6%
<u>Intrapartum</u>	<u>28</u>	<u>4%</u>		placental insufficiency	108 70%
<u>Trauma</u>	<u>2</u>	<u>0%</u>		other	10 6%
<u>Unclassified</u>	<u>130</u>	<u>20%</u>		<b>total</b>	<b>155 100%</b>
<u>Unknown</u>	<u>31</u>	<u>5%</u>			
<u>Total</u>	<u>656</u>	<u>100%</u>			
<u>not eligible</u>	<u>51*</u>				

**Wigglesworth/Hey classification <sup>22</sup>**

	<u>fetal</u>		<u>neonatal</u>		<u>unknown period</u>		<u>total</u>
<b><u>Delivery at</u></b>	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>	<u>n</u>
<u>37-40.6 wks</u>	<u>373</u>	<u>62%</u>	<u>217</u>	<u>36%</u>	<u>8</u>	<u>1%</u>	<u>598</u>
<u>≥ 41 wks</u>	<u>67</u>	<u>61%</u>	<u>42</u>	<u>39%</u>	<u>-</u>	<u>-</u>	<u>109</u>
<b><u>total</u></b>	<b><u>440</u></b>	<b><u>62%</u></b>	<b><u>259</u></b>	<b><u>37%</u></b>	<b><u>8</u></b>	<b><u>1%</u></b>	<b><u>707</u></b>

\* =during the first year missing data because of registration limitation for ReCoDe most relevant condition

**Table 4 Substandard factors (SSF) and relation to death in term perinatal death in 2010-2012**

relation to death§	2010		2011		2012		2010-2012		p-value*
	n	%	n	%	n	%	n	%	
cases with SSF	116	52%	147	54%	113	53%	376	53%	<u>0.92</u>
none/unlikely	45	20%	75	28%	63	30%	183	26%	<u>0.028</u>
possibly	28	13%	32	12%	32	15%	92	13%	<u>0.47</u>
(very) probably	23	10%	24	9%	10	5%	57	8%	<u>0.060</u>
unknown	20	9%	16	6%	8	4%	44	6%	<u>0.053</u>
cases without SSF	75	34%	97	36%	80	38%	252	36%	<u>0.71</u>
cases with insufficient information	31	14%	28	10%	20	9%	79	11%	<u>0.26</u>
Total cases	222	100%	272	100%	213	100%	707	100%	

§SSF=substandard factor

\* Chi-square test

**Table 5 Level of care Care type supervision at start of labour and period of death in term perinatal mortality and year of birth 2010-2012 in term perinatal mortality**

<u>supervision</u> <u>Level of care</u> <u>at start of labour</u>	perinatal death		foetal death		neonatal death	
	n	%	n	%	n	%
primary care	183	19%	101	11%	82	9%
secondary/tertiary care	730	77%	508	54%	222	24%
unknown	30	3%	4	0%	26	3%
Total	943	100%	613	65%	330	35%

  

year	primary care		secondary/tertiary care		unknown		total
	n	%	n	%	n	%	n
2010	68	21%	227	70%	29	9%	324
2011	69	21%	259	79%	1	0%	329
2012	46	16%	244	84%	0	0%	290
2010-2012	183	19%	730	77%	30	3%	943

p-value\*                      p=0.19                      p=0.001

\*Chi-square test

**Table 6 Characteristics of term perinatal mortality in PARS and PRN-Audit versus PRN 2010-2012**

Characteristics	PARS		PRN		p-value*
	n	%	n	%	
gestational age (weeks)					0.91
37.0-40.6	598	85%	930	84%	
≥41.0	109	15%	172	16%	
congenital malformations	135	19%	238	22%	0.20
moment of death					0.40
fetal	447	63%	718	65%	
neonatal	260	37%	384	35%	
unknown period	8	1%			
<b>Total</b>	<b>707</b>	<b>100%</b>	<b>1102</b>	<b>100%</b>	

  

Characteristics	PRN-Audit		PRN		p-value*
	n	%	n	%	
parity 0	450	48%	536	49%	0.68
age mother (years)					
<20	6	1%	11	1%	0.37
≥35	243	26%	292	26%	0.71
non-Caucasian ethnicity	185	20%	257	23%	0.04
congenital malformation	194	21%	238	22%	0.57
Period of death					0.94
fetal	613	65%	718	65%	
neonatal	330	35%	384	35%	
birth weight (grams)					
<2000	30	3%	60	5%	0.01
2000-2499	85	9%	98	9%	0.92
≥4500	22	2%	22	2%	0.60
gestational age (weeks)					
37.0-39.6	579	61%	707	64%	0.20
40.0-41.6	341	36%	371	34%	0.12
≥42.0	23	2%	24	2%	0.69
<b>Total</b>	<b>943</b>		<b>1102</b>		

PRN= perinatal registry of The Netherlands

PRN-Audit= perinatal audit registry of The Netherlands

PARS= perinatal audit registry system

\* Chi-square<sup>2</sup> test

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STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	v
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	v
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	v
Objectives	3	State specific objectives, including any prespecified hypotheses	v
Methods			
Study design	4	Present key elements of study design early in the paper	v
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	v
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	v
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	v
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	v
Bias	9	Describe any efforts to address potential sources of bias	v
Study size	10	Explain how the study size was arrived at	v
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	v
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	v
		(b) Describe any methods used to examine subgroups and interactions	n.a.
		(c) Explain how missing data were addressed	n.a.
		(d) If applicable, explain how loss to follow-up was addressed	n.a.
		(e) Describe any sensitivity analyses	n.a.
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	v
		(b) Give reasons for non-participation at each stage	n.a.
		(c) Consider use of a flow diagram	n.a.
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	v
		(b) Indicate number of participants with missing data for each variable of interest	v
		(c) Summarise follow-up time (eg, average and total amount)	v
Outcome data	15*	Report numbers of outcome events or summary measures over time	v
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which	n.a.

		confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	v
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n.a.
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n.a.
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	v
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	v
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	v
Generalisability	21	Discuss the generalisability (external validity) of the study results	v
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	v

\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.

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## Term perinatal mortality audit in The Netherlands 2010-2012: a population based cohort study

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**Term perinatal mortality audit in The Netherlands 2010-2012: a population based cohort study**

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Keywords: perinatal audit, perinatal care, term perinatal mortality, quality of perinatal care, substandard care factors, antepartum risk selection.

## ABSTRACT

### Objective

To assess the implementation and first results of term perinatal internal audit by a standardised method.

### Design

Population based cohort study.

### Setting

All 90 Dutch hospitals with obstetric/paediatric departments linked to community practices of midwives, general practitioners in their attachment areas, organised in perinatal cooperation groups (PCG).

### Population

The population existed of 943 registered term perinatal deaths occurring in 2010-2012 with detailed information, including 707 cases with completed audit results.

### Main outcome measures

Participation in audit, perinatal death classification, identification of substandard factors (SSF), SSF in relation to death, conclusive recommendations for quality improvement in perinatal care and antepartum risk selection at start of labour.

### Results

After the introduction of perinatal audit in 2010, all PCG's participated. They organised 645 audit sessions, with an average of 31 health care professionals per session.

Of all 1102 term perinatal deaths (2.3 per 1000) data were registered for 86% (943) and standardized anonymized audit results for 64% (707).

In 53% of the cases at least one SSF was identified. Non-compliance to guidelines (35%) and deviation from usual professional care (41%) were the most frequent SSF.

There was a (very) probable relation between the SSF and perinatal death for 8% of all cases. This declined over the years: from 10% (n=23) in 2010 to 5% (n=10) in 2012 (p=0.060). Simultaneously term perinatal mortality decreased from 2.3 to 2.0 per 1000 births (p<0.00001).

Possibilities for improvement were identified in the organisation of care (35%), guidelines or usual care (19%) and in documentation (15%).

More pregnancies were antepartum selected as high risk, 70% in 2010 and 84% in 2012 (p=0.0001).

### Conclusions

Perinatal audit is nationwide implemented in all obstetrical units in The Netherlands in a short time period. It is possible that audit contributed to the decrease in term perinatal mortality.

Strengths and limitations of this study

- The Netherlands is the first country in which all collaborating perinatal health care professionals nationwide participate in an internal perinatal audit systematically performed at the local level.
- Within two years all hospitals in the country providing obstetric/paediatric care with their surrounding midwifery practices participated in perinatal audit.
- Perinatal audit resulted in description of substandard factors (SSF), relation to death and the formulation of many recommendations mostly ready for implementation.
- Not all term perinatal deaths are audited. Characteristics of the audited cases are comparable to all term perinatal deaths in the national registration.
- Of all audited cases information was insufficient in 11% for substandard factor assessment. This is a major point of attention for the next years.

## Introduction

Perinatal mortality is an important indicator of the quality of perinatal care.<sup>1</sup> In 2000 The Netherlands had the highest perinatal mortality rate when compared to a large group of European countries.<sup>2,3</sup> Although perinatal mortality in The Netherlands has decreased in later years, in 2010 the ranking relative to other European countries showed only a modest improvement.<sup>4,5</sup>

These outcomes of the international benchmarks were an important incentive for Dutch politicians and professionals in the field of perinatal care to investigate the determinants of perinatal mortality including assessment of the quality of care. One of possible interventions in this regard is the introduction of perinatal audit, a critical and systematic analysis of the quality of perinatal care.<sup>6</sup> Earlier the introduction of perinatal audit in Norway has been an important factor in improving the quality of perinatal care and preceded a decline of perinatal mortality in Norway.<sup>7-9</sup>

In the Netherlands, perinatal audit studies were undertaken in the eighties of the past century. These audits were local or regional one-time studies.<sup>10-12</sup> More recently the professional organisations involved have jointly prepared the introduction of a nationwide perinatal mortality audit program that would become a standard part of perinatal care.<sup>13-17</sup> The Foundation Perinatal Audit in the Netherlands (PAN) was set up by the professional organisations of midwives, general practitioners, obstetricians, paediatricians, and pathologists ([www.perinataleaudit.nl](http://www.perinataleaudit.nl)). The first nationwide Dutch perinatal mortality audit has started in the period 2010-2012 with the focus on audit of term perinatal deaths.

PAN receives annual funding from the Ministry of Health of about € 900.000. A third of the budget is used for support of the perinatal cooperation groups (PCG's) by the regional teams. About 30% is intended for use and management of the registration systems and for reporting and communication (both including personnel costs). Another third is needed for the PAN office, board and advisory committees.

The objective of this study is to describe the implementation process of this perinatal audit program and to present the results after the first three years of term perinatal audit: perinatal death classification, antepartum high risk selection, identification of substandard (care) factors (SSF), SSF in relation to death and conclusive recommendations for quality improvement in perinatal care.

## Methods

### *Organisation and training*

A regional infrastructure with audit support teams has been set up. The teams consist of health care professionals in the 10 tertiary centres for perinatology with a neonatal intensive care unit



(NICU) and obstetric ‘high care’ department facilities. These regional teams were trained by PAN for coordination and support of the audit performance at local (hospital) levels. Subsequently these regional teams trained the audit teams of the local hospitals and the surrounding practices of independent community midwives and general practitioners within their region. PAN cooperated with the IMPACT project that pioneered the introduction of perinatal audit in the Northern region of The Netherlands.<sup>18</sup> PAN offered regular training sessions in organisation of audit, in making narratives, in chairing of the audit meeting and in classification of perinatal mortality. In January 2010 the nationwide Dutch perinatal mortality audit has officially started with the audit of term perinatal deaths as the first topic. This topic was chosen because of the involvement of all professional groups in the obstetric/paediatric/neonatal field in term pregnancies and deliveries. Within The Netherlands community midwives and, on a small scale, general practitioners provide obstetric care (including home birth) to women with antepartum judged low risk profiles. If complications (threaten to) occur the responsibility for obstetric care will be transferred to a medical specialist in a general hospital (secondary care) or tertiary centre. Risk selection during pregnancy and labour in primary or secondary/tertiary care is therefore the essence of the Dutch perinatal care organisation.<sup>19-21</sup>

The Netherlands is divided in 10 perinatal healthcare regions, catchment areas for perinatal high care centres which have NICU facilities. In 2012 there were 90 hospitals with obstetric/paediatric care facilities (97 in 2010 and 93 in 2011). Each hospital and the surrounding community practices of independent midwives and general practitioners are organised in a Perinatal Cooperation Group (PCG). Each PCG is responsible for auditing and registration of the mortality cases in their catchment area.

Representatives of the professionals of the PCG’s analyse the cases in a systematic way, identify substandard care factors (SSF) in delivered care and/or organisation of care, identify the types of professionals involved and classify mortality according to three different systems, i.e. the Wigglesworth /Hey, Modified ReCoDe and Tulip classifications.<sup>22-26</sup> During the audit the professionals relate the degree (non/unlikely, possible, (very) probable, unknown) to whether the SSF was causative for the death. Specific recommendations for improving the quality of care are then formulated. An independent chairperson presides the audit and provides a safe environment. He or she is a perinatal health care professional not practicing in the hospital/PCG where the audit takes place and is often a member of the regional audit team.

Audit with (involved) professionals is a delicate matter and needs careful procedures. The PAN has developed basic rules to enable a safe environment:

- Everything discussed during the audit is confidential. Every participant signs for this.
- Everybody is expert in his own professional field, participants can question professionals in other fields but do not judge them.

- The provided care and cure are assessed by comparing it to formal guidelines or usual care, not by one's own judgment.
- Narratives of the discussed cases that were drawn up before the meeting by members of the PCG are destroyed after the audit.

### *Definitions*

Term perinatal mortality is defined as stillbirth and neonatal mortality during the first four weeks of life in births with gestational age from 37.0 weeks onwards, including the post term period.<sup>27</sup> Cases with unknown gestational age were excluded.

A substandard factor (SSF) is present if care deviated from the safe limits of practice as laid down in national guidelines, local protocols (translation of national guidelines for local use) or normal professional practice.<sup>28</sup> The formal agreed guidelines are accessible at the websites of the professional organisations of the midwives (25 topics), obstetricians (63), paediatricians (29) and general practitioners (3). The agreed referral list for primary and secondary care (VIL, Obstetric Indication List) comprises 125 items<sup>14</sup> (translated in English)<sup>21</sup>. Most guidelines and the referral list items are covering term pregnancies as well. All agreed national guidelines in perinatology and the Obstetric Indication list are also available on the PAN website, arranged by professional organisation and by topic (<http://www.perinataleaudit.nl/bibliotheek/richtlijnen/aandoeningen>).

Antepartum low risk assessment is defined as antepartum judged low risk profile for care during labour and delivery by primary care professionals (community midwife or general practitioner), including delivery at home.<sup>19-21</sup>

### *Registries*

Because the audit focusses on recent cases that require more detailed and up to date information than is present in the national Dutch perinatal registry (PRN), two specific real-time databases were created to support the audit. The first for the registration of perinatal death cases to be audited (PRN-Audit, Perinatal Audit Registry of The Netherlands) and the second for the confidential registration of the audit process and its outcomes (PARS, Perinatal Audit Registry System).

#### **PRN-Audit database**

Term perinatal mortality deaths are registered in PRN-Audit by health care professionals. Data are gathered from the medical records and registered with specific details needed to construct the narrative that will be used during the audit. In PRN-Audit supplemental information is included such as professionals involved in the care process, diagnostics, policy decisions, actions (treatments, referrals) and antepartum risk selection with their time frames. The audit narrative, the basic document for the audit meeting, is automatically generated from the PRN-Audit database as an anonymous document.

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**PARS database**

The audit meetings (participants, number of cases discussed) and the outcomes of the audits are registered by the local audit groups in a separate database PARS. Because of privacy restrictions and to create a safe and secure environment for audit participants the PARS database is anonymous; only characteristics such as gestational age (categories) at birth, time (fetal-neonatal) of death and the perinatal death classifications are registered in PARS.

**PRN registry as reference**

The standard national PRN registry contains population-based information on all pregnancies, deliveries from 22 weeks onwards and (re)admissions occurring until 28 days after delivery. The data are collected by different professionals and are linked when year data sets are available which is 1,5 years afterwards. The PRN data is made available to healthcare providers, researchers and policymakers. The completeness of PRN is currently around 96-98% of all births ([www.perinatreg.nl](http://www.perinatreg.nl)).The national PRN database is the reference source for the audit cases in our study.

**Statistical methods**

Frequencies and descriptive statistics were expressed as n(%). For testing group differences, we used chi-square for categorical variables.

## Results

A total of 943/1102 (86%) of term perinatal deaths in the period 2010-2012 are registered in the PRN-Audit database and 707 (64%) cases were audited and recorded in the PARS database. Compared to the number of cases in the national perinatal registry PRN, the number of cases that were registered in the PRN-Audit database increased over the years (from 85% in 2010 to 89% in 2012  $p=0.04$ ) and the registration of cases in PARS showed an increase of 59% in 2010 to 66% in 2012  $p=0.015$  (table 1).

TABLE 1

### ***Number of audit meetings and participants***

Throughout The Netherlands 645 audit meetings took place in 2010-2012 with in total 20,091 participating health care professionals as community (independent) midwives, general practitioners, obstetricians, clinical midwives, nurses, paediatricians, pathologists, registrars, medical students and students in midwifery (with an average of 31 health care professionals per session). The number of participants nearly doubled in 2012 as compared to 2010. Half of the participants was once present, 15% twice and 35% three or more times. Audit participation of all the PCG's reached full coverage in the second year (2011) (table 1).

### ***Substandard factors***

In 53% (376) of the 707 audited cases one or more substandard factors (SSF) were identified (table 2a).

TABLE 2a

A total of 717 SSF's emerged. In 35% of the cases these were related to non-compliance with guidelines or missing appropriate local protocols and in 41 % they implied deviation from usual professional care (table 2b).

TABLE 2b

Examples of deviations from guidelines are: no or delayed consultation of the obstetrician in case of suspected fetal growth restriction, no fetal monitoring in case of induction of labour, expectant management in case of non-reassuring cardiotocography, non-optimal application of the guideline for resuscitation of the new born. Examples of deviation from usual professional care are: no fetal monitoring in case of vaginal blood loss, no consultation or action undertaken in case of decreased fetal movements, no further diagnosis and/or action in case of presumed growth restriction and insufficient documentation in the medical records (medication, diagnostic considerations and policy).

### ***Cause of death***

Autopsy was performed in 38% and pathological examination of the placenta in 77% of the term cases registered for audit. Table 3 gives the results of the death classifications.

TABLE 3

In the Tulip classification 36 % of cases the underlying cause of death is classified as ‘placental’ and sub-classified as placental pathology (development, parenchyma, localisation, 31%), followed by umbilical cord complications (28%) and placental bed pathology (28%). Congenital malformation was classified in 19% as the underlying cause of death. In 32% of cases the cause of death is unknown. Using the ReCoDe classifications placental pathology was the most important clinical condition (24%) with placental insufficiency (n=108) and placental abruptio for 26 cases as main groups. The Wigglesworth/Hey classification shows 62% fetal death and 15% of the pregnancies had a gestational age of  $\geq 41$  weeks (Table 3).

**SSF, relation to death and professional involvement**

In 8% (57) of the 707 audited cases the relation of SSF to death was assessed as probable or very probable and in 13% (92) as possible. The percentage of cases with one or more SSF remained stable during the years. Of these the cases with non/unlikely relation of SSF’s to death increased from 20% in 2010 to 30% in 2012 ( $p=0.028$ ) The rate of cases with SSF possibly related to death remained the same during the years, the cases with SSF (very) probably related to death decreased from 10% to 5% ( $p=0.060$ ) (table 4).

TABLE 4

In total 1269 health care professionals played a role in substandard factors in 376 cases: mean 3.4 professionals per case. Of them 26% was obstetrician, 20% independent community midwife and 12% clinical midwife. Nurses were involved in 10% of the cases, paediatricians in 7% and registrars in 10% of the cases.

**Antepartum low risk assessment**

For 19% (183) of all registered cases there was antepartum low risk selection for primary care delivery. Antepartum high risk assessment showed a significant increase from 70% to 84% ( $p=0.0001$ ) (table 5).

TABLE 5

**Recommendations from the audit**

A total of 512 SSF’s were identified in the 376 cases with one or more SSF’s: in 57% (213) of the cases one SSF, in 19% (73) two SSF’s and in 24% (90) three or more SSF’s. This leads to 603 recommendations: in 71% of all indicated SSF’s (512/717) one recommendation is described, and in 6% (41) two and sometimes three recommendations.

Recommendations were in 35 % about the organisation of care as well as for the quality of cooperation inside and outside the hospital between the different professional groups. In 19% the recommendations were for better use of guidelines and following usual care. The

recommendations for guidelines focussed on the development or adjustment of local protocols. In addition recommendations are given for producing local protocols for usual care. A specific frequently pronounced recommendation was the development of a national guideline for reduced fetal movements. In 15% the recommendations are about better documentation of the care process. The advices for better communication (11%) refers to improvement of communication between professionals in community and hospital care. For training and education (17%) recommendations were formulated, for instance training in neonatal resuscitation and in cardiotocography interpretation courses.<sup>26</sup>

On the website of PAN all recommendations are sorted in groups and extensively elaborated [www.perinataleaudit.nl/onderwerpen/204/uitwerking-van-aanbevelingen](http://www.perinataleaudit.nl/onderwerpen/204/uitwerking-van-aanbevelingen).

### ***Representativeness of the documented and audited cases***

Distribution of gestational age, congenital malformation and fetal-neonatal death are comparable in PARS and PRN registry (table 6).

Table 6
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The characteristics of the cases from 2010-2012 in PRN-Audit database and in the national PRN database are comparable with regard to the maternal characteristics like parity, maternal age and gestational age except for a lower percentage of women of non-Caucasian ethnicity ( $p=0.04$ ) and for less infants with birth weight  $<2000$  grams ( $p=0.01$ ) (table 6).

Discussion

The Netherlands is the first country with a nationwide perinatal audit that is now systematically performed by all collaborating perinatal health care professionals at the local level. Within two years all hospitals that provide perinatal care with the surrounding and adherent midwifery practices in the country participated in perinatal audit. It proved feasible to audit and register the results of 64% (707) of all term perinatal deaths, which was a well representative sample of all term perinatal deaths in the Netherlands. Perinatal audit resulted in description of substandard factors (SSF) and many recommendations mostly ready for implementation within the own perinatal cooperation groups .

During the three years audit period term perinatal mortality decreased from 2.3 to 2.0 per 1000 births ( $p<0.00001$ ) (table 1). The percentage of cases with one or more SSF's did not change during these years, but the percentage of cases without or with an unlikely relation of SSF's to death increased ( $p=0.028$ ). Antepartum high risk selection increased from 70% to 84% during the years ( $p=0.0001$ ).

Strengths and limitations

Audit by a multidisciplinary team of health care professionals themselves (internal audit), is a feasible way to increase implementation of the audit results/recommendations in local practice. In the chosen approach in the Netherlands an independent chairperson has proven instrumental to optimize audit performance.<sup>18</sup>

This study concerns term perinatal deaths of recent date, the last cases of 2012 were audited in June 2013. Most audits are performed within 3-6 months after death which minimizes the potential loss of knowledge/memory and details of the cases and circumstances that contributed.

Not all term cases of perinatal death are audited. Characteristics of the audited cases however are comparable to all term perinatal deaths in the national registration of the PRN, the registered cases were also comparable except for lesser cases with non-Caucasian ethnicity and lesser cases with birth weight< 2000 gram. This suggests that cases have not been avoided systematically or were lost for discussion in the audit.

Of all audited cases information was insufficient in 11% for SSF assessment. This percentage remained similar during the years and is a point of concern for the next years.

It is unknown whether all audit meetings take place in the most optimal and consistent way. However in our study the percentage of cases with assessed SSF's remained about the same during the years. In our view this fits with a stable audit method.

Knowledge of the outcome can influence the judgment of the care and the relation between the substandard factors and the outcome, especially when the outcome is perinatal death.<sup>29 30</sup>

Although participants could have assessed more or less harshly, the overall nationwide collected output of cases with SSF was quite consistent.



The cause of death according to the Tulip Classification was classified as unknown in 32% of the cases in our study. This high percentage suggests that improvement may be feasible by further training of the audit teams in using the Tulip classification in addition to the desirability of more autopsies and placenta biopsies.<sup>25 31</sup>

### ***Comparison with other studies***

There are no other studies with national internal perinatal audit programs, so we can only compare with earlier regional (external) audit studies.

### ***SSF***

In 36% of the audited cases in our study the audit group did not identify or assess any SSF. This is lower than in earlier regional studies in the Netherlands in 1996-1997 and 2003-2004 with 40-45%.<sup>12 15</sup> A possible explanation is that professionals are more critical about their own delivered care than external audit panels are. Otherwise these studies were performed 10 or even more years ago and in the meantime many guidelines are developed and could be used as reference for SSF.

In 11% of all cases insufficient information was present for SSF assessment. In earlier audit studies in The Netherlands this percentage was 2-4%.<sup>12 15</sup> However, these audits (and narratives) were prepared by one or two dedicated researchers while in the nationwide audit each perinatal cooperation group has to gather all information for the narrative during their daily work.

### ***SSF and relation to death***

The audit groups found a probable or very probable relation of substandard factors to death in 8% (n=57) of all discussed term perinatal deaths. In the LPAS-study, a regional external audit in 2003-2004 in the Netherlands, this was 9%.<sup>15</sup> In earlier studies (external audits) only the combined outcome of possible and probable relation of SSF and death is given. In 25-30% a combined possible or probable relation is found in The Netherlands and even 46% in 10 European regions in 1993-1998 (Euronatal study).<sup>1 11 12 30</sup> These combined percentages were higher than in our recent study (21%) and in the earlier LPAS-study (19%).<sup>15</sup> It is possible that these differences can be (partly) explained by quality of care improvement during the past 20 years. Otherwise it would be desirable to examine whether, compared to external review, our method of internal review with an external chair was more or less likely to identify SSF's with possible/probable relation to the death.

### ***Classification of perinatal death***

At 36% a placental cause of death in the Tulip classification was the most frequent. This is similar to the results of the LPAS study.<sup>15</sup> Comparison of the prevalence of perinatal death causes with other studies is difficult since those reports do not show the term period separately enough for



proper comparison. In an university clinic with preterm births included, 27% placental cause of death was found.<sup>25</sup>

*Implications of the study and further research*

A systematic method of perinatal audit has been implemented by all perinatal cooperation groups in The Netherlands. Audits generated many recommendations for quality of care improvements, which are in progress towards implementation. The infrastructure of perinatal audit in The Netherlands had been secured and more topics can be chosen in the future for audit in perinatal care. For the years 2013-2015 the focus is term intrapartum and neonatal death and admission to a neonatal intensive care unit for neonatal asphyxia.

Further evaluation of time trends on term perinatal mortality will be an important focus for the years 2013-15. The evaluation so far is based on only three years, which is rather short to draw conclusions about trends in a rare outcome as perinatal mortality.

It is assumed that the chance of uptake of actions formulated by local professionals themselves is greater than the uptake of top down imposed advice. In general the implementation of changes in care proves to be difficult.<sup>32</sup> At national level the professional organisations involved now cooperate in the college perinatal care (CPZ), instituted by the Ministry of Health

(<http://www.collegepz.nl/organisatie>). CPZ is coordinating desirable changes in perinatal care.

During the three years studied term perinatal mortality decreased. The percentage of cases with SSF without a relation to death increased while the percentage of cases with SSF and a probable relation to death decreased. Although a direct relationship cannot be proven, the parallel is striking with the synchrony of audit implementation and subsequently declining perinatal mortality in Norway.<sup>9</sup>

Antepartum high risk selection increased during the years 2010-2012. This can suggest that risk selection became more accurate but this needs further investigation.<sup>33</sup> Some recommendations from the audits have already been implemented such as the need for developing a new national guideline for 'reduced fetal movements'.<sup>34</sup>

**Conclusion**

Within a short time period a systematic method of internal perinatal audit has been implemented by all perinatal cooperation groups in The Netherlands. Audits performed by healthcare professionals themselves generated many recommendations for quality of care improvements which are in progress towards implementation. It is possible that audit contributed to the decrease in term perinatal mortality. With ongoing audits quality of perinatal care can be continuously monitored and instruments for quality of care improvement developed.

These findings can be a stimulus for introduction of nationwide internal perinatal audit in other countries and in other medical disciplines.

#### [acknowledgment]

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#### [Contributors]

Martine Eskes (guarantor), Adja Waelput, Jan Jaap Erwich, Hens Brouwers, Anita Ravelli, Peter Achterberg, Hans Merkus and Hein Bruinse had the core idea for this study. Anita Ravelli and Martine Eskes prepared and analysed the data and/or interpreted the results. Adja Waelput, Martine Eskes and Anita Ravelli wrote the draft of the article. Jan Jaap Erwich, Hens Brouwers, Peter Achterberg, Hans Merkus and Hein Bruinse commented on the manuscript and approved the final version.

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No funding for the study.

#### [Competing interest]

All authors have completed the Unified Competing Interest form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare: there was no support from any organisation for the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

#### [Ethics approval]

PARS is a complete anonymous registration, no data is traceable to patient and/or health care professional. Therefore no formal ethical approval procedure was waived.

The national perinatal registry of The Netherlands (PRN) provided data from the PRN and PRN-Audit, registered as data request 11.38, 13.45, 13.51, 13.61, 14.09 ([www.perinatereg.nl](http://www.perinatereg.nl)). The PRN has given permission for the analysis of their data.

#### [Datasharing]

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Dataset can be requested at the board of Foundation Perinatal Audit in The Netherlands (PAN) [info@perinataleaudit.nl](mailto:info@perinataleaudit.nl) .

[Transparency declaration]

Martine Eskes (the manuscript’s guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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**Table1 Term perinatal deaths and audit implementation parameters 2010-2012**

	2010		2011		2012		2010-2012		p value*
	n	%	n	%	n	%	n	%	
term born children (PRN)	163,276		163,248		160,714		487,238		
term death cases and rate (PRN)									
perinatal	379	0.23%	398	0.24%	325	0.20%	1102	0.23%	<0.00001
fetal	249	0.15%	252	0.15%	217	0.14%	718	0.15%	<0.00001
neonatal	130	0.08%	146	0.09%	108	0.07%	384	0.08%	<0.00001
term death cases in PRN-Audit	324	85%	329	83%	290	89%	943	86%	0.04
term death cases in PARS	222	59%	272	68%	213	66%	707	64%	0.015
number PCG's	97		93		90		-		
audit participation of PCG's	94	97%	93	100%	90	100%	-		
meetings	149		244		252		645		
participants	4,291		7,557		8,243		20,091		

PRN= perinatal registry of The Netherlands

PRN-Audit= perinatal audit registry of The Netherlands

PARS= perinatal audit registry system

PCG=perinatal cooperation groups (number decreased by closure of hospitals).

\*Chi-square test

**Table 2a Number of substandard factors (SSF) assessed per case of term perinatal death 2010-2012**

SSF per case	n	%
no SSF	252	36%
≥ 1 SSF	376	53%
1	213	30%
2	73	10%
3	43	6%
4	27	4%
≥5	20	3%
insufficient information	79	11%
<b>Total cases</b>	<b>707</b>	<b>100%</b>

**Table 2b Categories of all 717 substandard factors (SSF) in 376 term perinatal deaths of infants born in 2010-2012**

Category SSF	n	%
non-compliance of guidelines or local protocols missing	250	35%
deviation from usual professional care	294	41%
other	173	24%
<b>Total SSF</b>	<b>717*</b>	<b>100%</b>

SSF=substandard factor

\*per case more SSF's can be present

**Table 3 Tulip-classification, modified ReCoDe-classification and Wigglesworth/Hey classification of term perinatal deaths (2010-2012)**

**Tulip classification of perinatal mortality**

**(underlying cause of death, main groups and placental subgroups)<sup>25</sup>**

	n	%				
Congenital anomaly	135	19%				
<b>Placenta</b>	<b>253</b>	<b>36%</b>	→	<b>Placenta</b>		
Infection	32	5%		umbilical cord	70	28%
Other	52	7%		placental bed	71	28%
Unknown	224	32%		development	42	17%
no information	11	2%		parenchyma	31	12%
<b>Total</b>	<b>707</b>	<b>100%</b>		localisation	6	2%
				NOS	33	13%
				<b>Total</b>	<b>253</b>	<b>100%</b>

**Modified ReCoDe classification, most relevant condition at death (main groups and placental subgroups)<sup>23 24</sup>**

	n	%				
Fetus group	85	13%				
Neonate	129	20%				
Umbilical cord	60	9%				
<b>Placenta</b>	<b>155</b>	<b>24%</b>	→	<b>Placenta</b>		
amniotic fluid	4	1%		placental abruptio	26	17%
Uterus	6	1%		placenta praevia	2	1%
Mother	26	4%		vasa praevia	9	6%
Intrapartum	28	4%		placental insufficiency	108	70%
Trauma	2	0%		Other	10	6%
Unclassified	130	20%		<b>Total</b>	<b>155</b>	<b>100%</b>
Unknown	31	5%				
<b>Total</b>	<b>656</b>	<b>100%</b>				
not eligible	<b>51*</b>					

**Wigglesworth/Hey classification<sup>22</sup>**

	fetal		neonatal		unknown period		Total
Delivery at	n	%	n	%	n	%	n
37-40.6 wks	373	62%	217	36%	8	1%	598
≥ 41 wks	67	61%	42	39%	-	-	109
total	440	62%	259	37%	8	1%	<b>707</b>

\* =during the first year missing data because of registration limitation for ReCoDe most relevant condition

**Table 4 Substandard factors (SSF) and relation to death in term perinatal deaths in 2010-2012**

relation to death	2010		2011		2012		2010-2012		p value*
	n	%	n	%	n	%	n	%	
cases with SSF	116	52%	147	54%	113	53%	376	53%	0.92
none/unlikely	45	20%	75	28%	63	30%	183	26%	<b>0.028</b>
possible	28	13%	32	12%	32	15%	92	13%	0.47
(very) probable	23	10%	24	9%	10	5%	57	8%	0.060
unknown	20	9%	16	6%	8	4%	44	6%	0.053
cases without SSF	75	34%	97	36%	80	38%	252	36%	0.71
cases with insufficient information	31	14%	28	10%	20	9%	79	11%	0.26
Total cases	222	100%	272	100%	213	100%	707	100%	

SSF=substandard factor

\* Chi-square test

**Table 5 Level of care at start of labour, period of death and year of birth in term perinatal deaths**

Level of care at start of labour	perinatal death		fetal death		neonatal death	
	n	%	n	%	N	%
primary care	183	19%	101	11%	82	9%
secondary/tertiary care	730	77%	508	54%	222	24%
unknown	30	3%	4	0%	26	3%
Total	943	100%	613	65%	330	35%

  

	primary care		secondary/tertiary care		Unknown		total
year	n	%	n	%	n	%	n
2010	68	21%	227	70%	29	9%	324
2011	69	21%	259	79%	1	0%	329
2012	46	16%	244	84%	0	0%	290
2010-2012	183	19%	730	77%	30	3%	943
p-value*	p=0.19		p=0.0001				

\*Chi-square test



**Table 6 Characteristics of term perinatal deaths in PARS and PRN-Audit versus PRN 2010-2012**

Characteristics	PARS		PRN		p-value*
	n	%	n	%	
gestational age (weeks)					0.91
37.0-40.6	598	85%	930	84%	
≥41.0	109	15%	172	16%	
congenital malformations	135	19%	238	22%	0.20
moment of death					0.40
fetal	440	62%	718	65%	
neonatal	259	37%	384	35%	
unknown period	8	1%			
<b>Total</b>	<b>707</b>	<b>100%</b>	<b>1102</b>	<b>100%</b>	

  

Characteristics	PRN-Audit		PRN		p-value*
	n	%	n	%	
parity 0	450	48%	536	49%	0.68
age mother (years)					
<20	6	1%	11	1%	0.37
≥35	243	26%	292	26%	0.71
non-Caucasian ethnicity	185	20%	257	23%	<b>0.04</b>
congenital malformation	194	21%	238	22%	0.57
period of death					0.94
fetal	613	65%	718	65%	
neonatal	330	35%	384	35%	
birth weight (grams)					
<2000	30	3%	60	5%	<b>0.01</b>
2000-2499	85	9%	98	9%	0.92
≥4500	22	2%	22	2%	0.60
gestational age (weeks)					
37.0-39.6	579	61%	707	64%	0.20
40.0-41.6	341	36%	371	34%	0.12
≥42.0	23	2%	24	2%	0.69
<b>Total</b>	<b>943</b>		<b>1102</b>		

PRN= perinatal registry of The Netherlands  
PRN-Audit= perinatal audit registry of The Netherlands  
PARS= perinatal audit registry system  
\* Chi-square test

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## Term perinatal mortality audit in The Netherlands 2010-2012: a population based cohort study

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Keywords: perinatal audit, perinatal care, term perinatal mortality, quality of perinatal care, substandard care factors, antepartum risk selection.

**ABSTRACT**

**Objective**

To assess the implementation and first results of term perinatal internal audit by a standardised method.

**Design**

Population based cohort study.

**Setting**

All 90 Dutch hospitals with obstetric/-paediatric departments linked to community practices of midwives, general practitioners in their attachment areas, organised in perinatal cooperation groups (PCG) ~~participated in the study.~~

**Population**

The population existed of 943 registered ~~cases of~~ term perinatal deaths occurring in 2010-2012 with detailed information, including 707 cases with completed audit results.

**Main outcome measures**

Participation in audit, perinatal death classification, identification of substandard factors (SSF), SSF in relation to death, conclusive recommendations for quality improvement in perinatal care and antepartum risk selection at start of labour.

**Results**

After the introduction of perinatal audit in 2010, all PCG's participated. They organised 645 audit sessions, with an average of 31 health care professionals per session.

Of all 1102 term perinatal deaths (2.3 per 1000) data were registered for 86% (943) and standardized anonymized audit results for 64% (707).

In 53% of the cases at least one SSF was identified. Non-compliance to guidelines (35%) and ~~nonobservance of deviation from~~ usual professional care (41%) were the most frequent SSF.

There was a (very) probable relation between the SSF and perinatal death for 8% of all cases. This declined over the years: from 10% (n=23) in 2010 to 5% (n=10) in 2012 (p=0.060). Simultaneously term perinatal mortality decreased from 2.3 to 2.0 per 1000 births (p<0.00001).

Possibilities for improvement were identified in the organisation of care (35%), guidelines or usual care (19%) and in documentation (15%).

More pregnancies were antepartum selected as high risk, 70% in 2010 and 84% in 2012 (p=0.0001).

**Conclusions**

Perinatal audit is nationwide implemented in all obstetrical units in The Netherlands in a short time period. It is possible that audit contributed to the decrease in term perinatal mortality.

## Strengths and limitations of this study

- The Netherlands is the first country in which all collaborating perinatal health care professionals nationwide participate in an internal perinatal audit systematically performed at the local level.
- Within two years all hospitals in the country providing obstetric/paediatric care with their surrounding midwifery practices participated in perinatal audit.
- Perinatal audit resulted in description of substandard factors (SSF), relation to death and the formulation of many recommendations mostly ready for implementation.
- Not all term perinatal deaths are audited. Characteristics of the audited cases are comparable to all term perinatal ~~mortality cases~~ deaths in the national registration.
- Of all audited cases information was insufficient in 11% for substandard factor assessment. This is a major point of attention for the next years.

Introduction

Perinatal mortality is an important indicator of the quality of perinatal care.<sup>1</sup> In 2000 The Netherlands had the highest perinatal mortality rate when compared to a large group of European countries.<sup>2,3</sup> Although perinatal mortality in The Netherlands has decreased in later years, in 2010, the ranking relative to other European countries showed only a modest improvement.<sup>4,5</sup> These outcomes of the international benchmarks were an important incentive for Dutch politicians and professionals in the field of perinatal care to investigate the determinants of perinatal mortality including assessment of the quality of care. One of possible interventions in this regard is the introduction of perinatal audit, a critical and systematic analysis of the quality of perinatal care.<sup>6</sup> Earlier the introduction of perinatal audit in Norway has been an important factor in improving the quality of perinatal care and preceded a decline of perinatal mortality in Norway.<sup>7-9</sup> In the Netherlands, perinatal audit studies were undertaken in the eighties of the past century. These audits were local or regional one-time studies.<sup>10-12</sup> More recently the professional organisations involved have jointly prepared the introduction of a nationwide perinatal mortality audit program that would become a standard part of perinatal care.<sup>13-17</sup> The Foundation Perinatal Audit in the Netherlands (PAN) was set up by the professional organisations of midwives, general practitioners, obstetricians, paediatricians, and pathologists ([www.perinataleaudit.nl](http://www.perinataleaudit.nl)). The first nationwide Dutch perinatal mortality audit has started in the period 2010-2012 with the focus on audit of term perinatal [mortalitydeaths](#). PAN receives annual funding from the Ministry of Health of about € 900.000. A third of the budget is used for support of the perinatal cooperation groups (PCG's) by the regional teams. About 30% is intended for use and management of the registration systems and for reporting and communication (both including personnel costs). Another third is needed for the PAN office, board and advisory committees. The objective of this study is to describe the implementation process of this perinatal audit program and to present the results after the first three years of term perinatal audit: perinatal death classification, antepartum high risk selection, identification of substandard (care) factors (SSF), SSF in relation to death and conclusive recommendations for quality improvement in perinatal care.

Methods

Organization and training

A regional infrastructure with audit support teams has been set up. The teams consist of health care professionals in the 10 tertiary centres for perinatology with a neonatal intensive care unit



(NICU) and obstetric 'high care' department facilities. These regional teams were trained by PAN for coordination and support of the audit performance at local (hospital) levels. Subsequently these regional teams trained the audit teams of the local hospitals and the surrounding practices of independent community midwives and general practitioners within their region. PAN cooperated with the IMPACT project that pioneered the introduction of perinatal audit in the Northern region of The Netherlands.<sup>18</sup> PAN offered regular training sessions in organisation of audit, in making narratives, in chairing of the audit meeting and in classification of perinatal mortality.

In January 2010 the nationwide Dutch perinatal mortality audit has officially started with the audit of term perinatal [mortality deaths](#) as the first topic. [Term perinatal mortality](#) This topic was chosen because of the involvement ~~in term pregnancies and deliveries~~ of all professional groups in the obstetric/paediatric/neonatal field [in term pregnancies and deliveries](#). Within The Netherlands community midwives and, on a small scale, general practitioners provide obstetric care (including home birth) to women with antepartum judged low risk profiles. If complications (threaten to) occur the responsibility for obstetric care will be transferred to a medical specialist in a general hospital (secondary care) or tertiary centre. Risk selection during pregnancy and labour in primary or secondary/tertiary care is therefore the essence of the Dutch perinatal care organisation.<sup>19-21</sup>

The Netherlands is divided in 10 perinatal healthcare regions, catchment areas for perinatal high care centres which have NICU facilities. In 2012 there were 90 hospitals with obstetric/paediatric care facilities (97 in 2010 and 93 in 2011). Each hospital and the surrounding community practices of independent midwives and general practitioners are organised in a Perinatal Cooperation Group (PCG). Each PCG is responsible for auditing and registration of the mortality cases in their catchment area.

Representatives of the professionals of the PCG's analyse the cases in a systematic way, identify substandard care factors (SSF) in delivered care and/or organisation of care, identify the types of professionals involved and classify mortality according to three different systems, i.e. the Wigglesworth /Hey, Modified ReCoDe and Tulip classifications.<sup>22-26</sup> During the audit the professionals relate the degree (non/unlikely, possible, [\(very\)](#) probable, unknown) to whether the SSF was causative for the death. Specific recommendations for improving the quality of care are then formulated. An independent chairperson presides the audit and provides a safe environment. He or she is a perinatal health care professional not practicing in the hospital/PCG where the audit takes place and is often a member of the regional audit team.

Audit with (involved) professionals is a delicate matter and needs careful procedures. The PAN has developed basic rules to enable a safe environment:

- Everything discussed during the audit is confidential. Every participant signs for this.
- Everybody is expert in his own professional field, participants can question professionals in other fields but do not judge them.



- The provided care and cure are assessed by comparing it to formal guidelines or usual care, not by one's own judgment.
- Narratives of the discussed cases that were drawn up before the meeting by members of the PCG are destroyed after the audit.

*Definitions*

Term perinatal mortality is defined as stillbirth and neonatal mortality during the first four weeks of life in births with gestational ages from 37.0 weeks onwards, including the post term period.<sup>27</sup>

Cases with unknown gestational age were excluded.

A substandard factor (SSF) is present if care ~~that~~ deviated from the safe limits of practice as laid down in national guidelines, - local protocols (translation of national guidelines for local use) or normal professional practice.<sup>28</sup> The formal agreed guidelines are accessible at the websites of the professional organisations of the midwives (25 topics), obstetricians (63), paediatricians (29) and general practitioners (3). The agreed referral list for primary and secondary care (VIL, Obstetric Indication List) comprises 125 items<sup>14</sup> (translated in English)<sup>21</sup>. Most guidelines and the referral list items are covering term pregnancies as well. All agreed national guidelines in perinatology and the Obstetric Indication list are also available on the PAN website, arranged by professional organisation and by topic (<http://www.perinataleaudit.nl/bibliotheek/richtlijnen/aandoeningen>).

Antepartum low risk assessment is defined as antepartum judged low risk profile for care during labour and delivery by primary care professionals (community midwife or general practitioner), including delivery at home.<sup>19-21</sup>

*Registries*

Because the audit focusses on recent cases that require more detailed and up to date information than is present in the national Dutch perinatal registry (PRN), two specific real-time databases were created to support the audit. The first for the registration of perinatal death cases to be audited (PRN-Audit, Perinatal Audit Registry of The Netherlands) and the second for the confidential registration of the audit process and its outcomes (PARS, Perinatal Audit Registry System).

**PRN-Audit database**

Term perinatal mortality cases-deaths are registered in PRN-Audit by health care professionals. Data are gathered from the medical records and registered with specific details needed to construct the narrative that will be used during the audit. In PRN-Audit supplemental information is included such as professionals involved in the care process, diagnostics, policy decisions, actions (treatments, referrals) and antepartum risk selection with their time frames. The audit narrative, the basic document for the audit meeting, is automatically generated from the PRN-Audit database as an anonymous document.

## PARS database

The audit meetings (participants, number of cases discussed) and the outcomes of the audits are registered by the local audit groups in a separate database PARS. Because of privacy restrictions and to create a safe and secure environment for audit participants the PARS database is anonymous; only characteristics such as gestational age (categories) at birth, time (fetal-neonatal) of death and the perinatal death classifications are registered in PARS.

## PRN registry as reference

The standard national PRN registry contains population-based information on all pregnancies, deliveries from 22 weeks onwards and (re)admissions occurring until 28 days after delivery. The data are collected by different professionals and are linked when year data sets are available which is 1,5 years afterwards. The PRN data is made available to healthcare providers, researchers and policymakers. The completeness of PRN is currently around 96-98% of all births ([www.perinatreg.nl](http://www.perinatreg.nl)). The national PRN database is the reference source for the audit cases in our study.

## Statistical methods

~~The study is descriptive. Frequencies and descriptive statistics were expressed as n(%). For testing group differences, we used chi-square for categorical variables. For the comparison of characteristics in the PRN registry with the characteristics in the PRN-Audit/ PARS database, as for trend of time, a chi-squared test is used.~~

Results

A total of 943/1102 (86%) ~~cases~~ of term perinatal ~~mortality cases~~~~deaths~~ in the period 2010-2012 are registered in the PRN-Audit database and 707 (64%) cases were audited and recorded in the PARS database. Compared to the number of cases in the national perinatal registry PRN, the number of cases that were registered in the PRN-Audit database increased over the years (from 85% in 2010 to 89% in 2012  $p=0.009804$ ) and the registration of cases in PARS showed an increase of 59% in 2010 to 66% in 2012  $p=0.015$  (table 1).

TABLE 1

*Number of audit meetings and participants*

Throughout The Netherlands 645 audit meetings took place in 2010-2012 with in total 20,091 participating health care professionals as community (independent) midwives, general practitioners, obstetricians, clinical midwives, nurses, paediatricians, pathologists, registrars, medical students and students in midwifery (with an average of 31 health care professionals per session). The number of participants nearly doubled in 2012 as compared to 2010. Half of the participants was once present, 15% twice and 35% three or more times. Audit participation of all the PCG's reached full coverage in the second year (2011) (table 1).

*Substandard factors*

In 53% (376) of the 707 audited cases one or more substandard factors (SSF) were identified (table 2a).

TABLE 2a

A total of 717 SSF's emerged. In 35% of the cases these were related to non-compliance with guidelines or missing appropriate local protocols and in 41 % they implied ~~nonobservance of~~ deviation from usual professional care (table 2b).

TABLE 2b

Examples of deviations ~~of from~~ from guidelines are: no or delayed consultation of the obstetrician in case of suspected fetal growth restriction, no fetal monitoring in case of induction of labour, expectant management in case of non-reassuring cardiotocography, non-optimal application of the guideline for resuscitation of the new born. Examples of deviation ~~from of~~ from usual professional care are: no fetal monitoring in case of vaginal blood loss, no consultation or action undertaken in case of decreased fetal movements, no further diagnosis and/or action in case of presumed growth restriction and insufficient documentation in the medical records (medication, diagnostic considerations and policy).

*Cause of death*

Autopsy was performed in 38% and pathological examination of the placenta in 77% of the term cases registered for audit. Table 3 gives the results of the death classifications.

TABLE 3

In the Tulip classification 36 % of cases the underlying cause of death is classified as 'placental' and sub-classified as placental pathology ([development, parenchyma, localisation](#), (31%), followed by umbilical cord complications (28%) and placental bed pathology (28%). Congenital malformation was classified in 19% as the underlying cause of death. In 32% of cases the cause of death is unknown. Using the ReCoDe classifications placental pathology was the most important clinical condition (24%) with placental insufficiency (n=108) and [placental](#) [abruption](#) for 26 cases as main groups. The Wigglesworth/Hey classification shows 62% fetal death and 15% of the pregnancies had a gestational age of  $\geq 41$  weeks (Table 3).

### ***SSF, relation to death and professional involvement***

In 8% (57) of the 707 audited cases the relation of SSF to death was assessed as probable [or very probable](#) and in 13% (92) as possible. The percentage of cases with one or more SSF remained stable during the years. Of these the cases with non/unlikely relation of SSF's to death increased from 20% in 2010 to 30% in 2012 ( $p=0.028$ ) The rate of cases with SSF possibly related to death remained the same during the years, the cases with SSF (very) probably related to death decreased from 10% to 5% ( $p=0.060$ ) (table 4).

TABLE 4

In total 1269 health care professionals played a role in substandard factors in 376 cases: mean 3.4 professionals per case. Of them 26% ~~were~~ [was](#) obstetrician, 20% independent community midwife and 12% ~~a~~-clinical midwife. Nurses were involved in 10% of the cases, paediatricians in 7% and registrars in 10% of the cases.

### ***Antepartum low risk assessment***

For 19% (183) of all registered cases there was antepartum low risk ~~selection~~ for primary care delivery. Antepartum high risk assessment showed a significant increase from 70% to 84% ( $p=0.0001$ ) (table 5).

TABLE 5

### ***Recommendations from the audit***

A total of 512 SSF's were identified in the 376 cases with one or more SSF's: in 57% (213) of the cases one SSF, in 19% (73) two SSF's and in 24% (90) three or more SSF's. This leads to 603 recommendations: in 71% of all indicated SSF's (512/717) one recommendation is described, and in 6% (41) two and sometimes three recommendations.

Recommendations were in 35 % about the organisation of care as well as for the quality of cooperation inside and outside the hospital between the different professional groups. In 19% the recommendations were for better use of guidelines and following usual care. The

recommendations for guidelines focussed on the development or adjustment of local protocols. In addition recommendations are given for producing local protocols for usual care. A specific frequently pronounced recommendation was the development of a national guideline for reduced fetal movements. In 15% the recommendations are about better documentation of the care process. The advices for better communication (11%) refers to improvement of communication between professionals in community and hospital care. For training and education (17%) recommendations were formulated, for instance training in neonatal resuscitation and in cardiotocography interpretation courses.<sup>26</sup>

On the website of PAN all recommendations are sorted in groups and extensively elaborated <http://www.perinataleaudit.nl/onderwerpen/204/uitwerking-van-aanbevelingen>.

**Representativeness of the documented and audited cases**

Distribution of gestational age, congenital malformation and fetal-neonatal death are comparable in PARS and PRN registry (table 6).

Table 6
---------

The characteristics of the cases from 2010-2012 in PRN-Audit database and in the national PRN database are comparable with regard to the maternal characteristics like parity, maternal age and gestational age except for a lower percentage of women of non-Caucasian ethnicity (p=0.04) and ~~ef~~ for less infants with birth weight <2000 grams (p=0.01) (table 6).

## Discussion

The Netherlands is the first country with a nationwide perinatal audit that is now systematically performed by all collaborating perinatal health care professionals at the local level. Within two years all hospitals that provide perinatal care with the surrounding and adherent midwifery practices in the country participated in perinatal audit. It proved feasible to audit and register the results of 64% (707) of all ~~cases of term perinatal~~term perinatal deaths, which was a well representative sample of all term perinatal deaths in the Netherlands. Perinatal audit resulted in description of substandard factors (SSF) and many recommendations mostly ready for implementation within the own perinatal cooperation groups .

During the three years audit period term perinatal mortality decreased from 2.3 to 2.0 per 1000 births ( $p < 0.00001$ ) (table 1). The percentage of cases with one or more SSF's did not change during these years, but the percentage of cases without or with an unlikely relation of SSF's to death increased ( $p = 0.028$ ). Antepartum high risk selection increased from 70% to 84% during the years ( $p = 0.0001$ ).

### **Strengths and limitations**

Audit by a multidisciplinary team of ~~the~~ health care professionals themselves (internal audit), is a feasible way to increase implementation of the audit results/recommendations in local practice. In the chosen approach in the Netherlands an independent chairperson has proven instrumental to optimize audit performance.<sup>18</sup>

This study concerns term perinatal deaths ~~s cases~~ of recent date, the last cases of 2012 were audited in June 2013. Most audits are performed within 3-6 months after death which minimizes the potential loss of knowledge/memory and details of the cases and circumstances that contributed.

Not all term cases of perinatal death are audited. Characteristics of the audited cases however are comparable to all term perinatal deaths ~~s cases~~ in the national registration of the PRN, the registered cases were also comparable except for lesser cases with non-Caucasian ethnicity and lesser cases with birth weight < 2000 gram. This suggests that cases have not been avoided systematically or were lost for discussion in the audit.

Of all audited cases information was insufficient in 11% for SSF assessment. This percentage remained similar during the years and is a point of concern for the next years.

It is unknown whether all audit meetings take place in the most optimal and consistent way.

However in our study the percentage of cases with assessed SSF's remained about the same during the years. In our view this fits with a stable audit method.

Knowledge of the outcome can influence the judgment of the care and the relation between the substandard factors and the outcome, especially when the outcome is perinatal death.<sup>29 30</sup>

Although participants could have ~~been assessed too much or too~~more or less harshly less severe ~~in their judgements~~, the overall nationwide collected output of cases with SSF was quite consistent.

The cause of death according to the Tulip Classification was classified as unknown in 32% of the cases in our study. This high percentage suggests that improvement may be feasible by further training of the audit teams in using the Tulip classification ~~apart from~~ in addition to the desirability of more autopsies and placenta biopsies.<sup>25 31</sup>

**Comparison with other studies**

There are no other studies with national internal perinatal audit programs, so we can only compare with earlier regional (external) audit studies.

**SSF**

In 36% of the audited cases in our study the audit group did not identify or assess any SSF. This is lower than in earlier regional studies in the Netherlands in 1996-1997 and 2003-2004 with 40-45%.<sup>12 15</sup> A possible explanation is that professionals are more critical about their own delivered care than external audit panels are. Otherwise these studies were performed 10 or even more years ago and in the meantime many guidelines are developed and could be used as reference for SSF.

In 11% of all cases insufficient information was present for SSF assessment. In earlier audit studies in The Netherlands this percentage was 2-4%.<sup>12 15</sup> However, these audits (and narratives) were prepared by one or two dedicated researchers while in the nationwide audit each perinatal cooperation group has to gather all information for the narrative during their daily work.

**SSF and relation to death**

The audit groups found a probable or very probable relation of substandard factors to death in 8% (n=57) of all discussed term perinatal death s-cases. In the LPAS-study, a regional external audit in 2003-2004 in the Netherlands, this was 9%.<sup>15</sup> In earlier studies (external audits) only the combined outcome of possible and probably-probable relation of SSF and death is given. In 25-30% a combined possible or probable ey relation is found in The Netherlands and even 46% in 10 European regions in 1993-1998 (Euronatal study).<sup>1 11 12 30</sup> These combined percentages were higher than in our recent study (21%) and in the earlier LPAS-study (19%).<sup>15</sup> It is possible that these differences can be (partly) explained by quality of care improvement during the past 20 years. Otherwise it would be desirable to examine whether, compared to external review, our method of internal review with an external chair was more or less likely to identify SSF's with possible/probable relation to the death.

**Classification of perinatal death**

At 36% a placental cause of death in the Tulip classification was the most frequent. This is similar to the results of the LPAS study.<sup>15</sup> Comparison of the prevalence of perinatal death causes with



other studies is difficult since those reports do not show the term period separately enough for proper comparison. In a perinatal death cohort of an university clinic with preterm births included, 27% placental cause of death was found.<sup>25</sup>

Comparison of the prevalence of the found causes with other studies is difficult, since other reports on the classification of a cohort of perinatal death do not show the term period separately enough for proper comparison.

### *Implications of the study and further research*

A systematic method of perinatal audit has been implemented by all perinatal cooperation groups in The Netherlands. Audits generated many recommendations for quality of care improvements, which are in progress towards implementation. The infrastructure of perinatal audit in The Netherlands had been secured and more topics can be chosen in the future for audit in perinatal care such as preterm mortality or specific morbidity. For the years 2013-2015 the focus is term intrapartum and neonatal death and admission to a neonatal intensive care unit for neonatal asphyxia.

Further evaluation of time trends on term perinatal mortality will be an important focus for the years 2013-15. The evaluation so far is based on only three years, which is rather short to draw conclusions about trends in a rare outcome as perinatal mortality.

It is assumed that the chance of uptake of actions formulated by local professionals themselves is greater than the uptake of top down imposed advice. In general the implementation of changes in care proves to be difficult.<sup>32</sup> At national level the professional organizations involved now cooperate in the college perinatal care (CPZ), instituted by the Ministry of Health (<http://www.collegepz.nl/organisatie>). CPZ is coordinating desirable changes in perinatal care. During the three years studied term perinatal mortality decreased. The percentage of cases with SSF without a relation to death increased while the percentage of cases with SSF and a probable relation to death decreased. Although a direct relationship cannot be proved, the parallel is striking with the synchrony of audit implementation and subsequently declining perinatal mortality in Norway is striking.<sup>9</sup>

Antepartum high risk selection increased during the years 2010-2012. This can suggest that risk selection became more accurate but this needs further investigation.<sup>33</sup> Some recommendations from the audits have already been implemented such as the need for developing a new national guideline for 'reduced fetal movements'.<sup>34</sup>

### **Conclusion**

Within a short time period a systematic method of internal perinatal audit has been implemented by all perinatal cooperation groups in The Netherlands. Audits performed by healthcare professionals themselves generated many recommendations for quality of care improvements which are in



progress towards implementation. It is possible that audit contributed to the decrease in term perinatal mortality. With ongoing audits quality of perinatal care can be continuously monitored and instruments for quality of care improvement developed. These findings can be a stimulus for introduction of nationwide internal perinatal audit in other countries and in other medical disciplines.

[acknowledgment]

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[Contributors]

Martine Eskes (guarantor), Adja Waelput, Jan Jaap Erwich, Hens Brouwers, Anita Ravelli, Peter Achterberg, Hans Merkus and Hein Bruinse had the core idea for this study. Anita Ravelli and Martine Eskes prepared and analysed the data and/or interpreted the results. Adja Waelput, Martine Eskes and Anita Ravelli wrote the draft of the article. Jan Jaap Erwich, Hens Brouwers, Peter Achterberg, Hans Merkus and Hein Bruinse commented on the manuscript and approved the final version.

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All authors have completed the Unified Competing Interest form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare: there was no support from any organization for the submitted work, no financial relationships with any organizations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

[Ethics approval]

PARS is a complete anonymous registration, no data is traceable to patient and/or health care professional. Therefore no formal ethical approval procedure was waived.

The national perinatal registry of The Netherlands (PRN) provided data from the PRN and PRN-Audit, registered as data request 11.38, 13.45, 13.51, 13.61, 14.09 ([www.perinatreg.nl](http://www.perinatreg.nl)). The PRN has given permission for the analysis of their data.

#### [Datasharing]

Dataset can be requested at the board of Foundation Perinatal Audit in The Netherlands (PAN) [info@perinataleaudit.nl](mailto:info@perinataleaudit.nl).

#### [Transparency declaration]

Martine Eskes (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Table1 Term perinatal deaths cases and audit implementation parameters 2010-2012

	2010		2011		2012		2010-2012		p value*
	n	%	n	%	n	%	n	%	
term born children (PRN)	163,276		163,248		160,714		487,238		value*
term death cases and rate (PRN)									
perinatal	379	0.23%	398	0.24%	325	0.20%	1102	0.23%	<0.00001
fetal	249	0.15%	252	0.15%	217	0.14%	718	0.15%	<0.00001
neonatal	130	0.08%	146	0.09%	108	0.07%	384	0.08%	<0.00001
term death cases in PRN-Audit	324	85%	329	83%	290	89%	943	86%	0.009804
term death cases in PARS	222	59%	272	68%	213	66%	707	64%	0.0147015
number PCG's	97		93		90		-		
audit participation of PCG's	94	97%	93	100%	90	100%	-		
meetings	149		244		252		645		
participants	4,291		7,557		8,243		20,091		

PRN= perinatal registry of The Netherlands

PRN-Audit= perinatal audit registry of The Netherlands

PARS= perinatal audit registry system

PCG=perinatal cooperation groups (number decreased by closures of hospitals).

\*Chi-square test

**Table 2a Number of substandard factors (SSF) assessed per case of term perinatal death 2010-2012**

SSF per case	n	%
no SSF	252	36%
≥ 1 SSF	376	53%
1	213	30%
2	73	10%
3	43	6%
4	27	4%
≥5	20	3%
insufficient information	79	11%
<b>Total cases</b>	<b>707</b>	<b>100%</b>

**Table 2b Categories of all 717 substandard factors (SSF) in 376 term perinatal deaths of infants born in 2010-2012**

Category SSF	n	%
non-compliance of guidelines or local protocols missing	250	35%
<del>Nonobservance-deviation from of</del> usual professional care	294	41%
other	173	24%
<b>Total SSF</b>	<b>717*</b>	<b>100%</b>

SSF=substandard factor

\*per case more SSF's can be present

Table 3 Tulip-classification, modified ReCoDe-classification and Wigglesworth/Hey classification of term perinatal deaths (2010-2012)

Tulip classification of perinatal mortality (underlying cause of death, main groups and placental subgroups) <sup>25</sup>						
	n	%				
Congenital anomaly	135	19%				
<b>Placenta</b>	<b>253</b>	<b>36%</b>	→	<b>Placenta</b>		
Infection	32	5%		umbilical cord	70	28%
Other	52	7%		placental bed	71	28%
Unknown	224	32%		development	42	17%
no information	11	2%		parenchyma	31	12%
<b>Total</b>	<b>707</b>	<b>100%</b>		localisation	6	2%
				NOS	33	13%
				<b>Total</b>	<b>253</b>	<b>100%</b>
Modified ReCoDe classification, most relevant condition at death (main groups and placental subgroups) <sup>23 24</sup>						
	n	%				
Fetus group	85	13%				
Neonate	129	20%				
Umbilical cord	60	9%				
<b>Placenta</b>	<b>155</b>	<b>24%</b>	→	<b>Placenta</b>		
amniotic fluid	4	1%		Abruptio placental		
Uterus	6	1%		abruptio	26	17%
Mother	26	4%		placenta praevia	2	1%
Intrapartum	28	4%		vasa praevia	9	6%
Trauma	2	0%		placental insufficiency	108	70%
Unclassified	130	20%		Other	10	6%
Unknown	31	5%		<b>Total</b>	<b>155</b>	<b>100%</b>
<b>Total</b>	<b>656</b>	<b>100%</b>				
not eligible	<b>51*</b>					
Wigglesworth/Hey classification <sup>22</sup>						
Delivery at	fetal		neonatal		unknown period	
	n	%	n	%	n	%
37-40.6 wks	373	62%	217	36%	8	1%
≥ 41 wks	67	61%	42	39%	-	-
total	440	62%	259	37%	8	1%

\* =during the first year missing data because of registration limitation for ReCoDe most relevant condition

**Table 4 Substandard factors (SSF) and relation to death in term perinatal deaths in 2010-2012**

relation to death	2010		2011		2012		2010-2012		p value*
	n	%	n	%	n	%	n	%	
cases with SSF	116	52%	147	54%	113	53%	376	53%	0.92
none/unlikely	45	20%	75	28%	63	30%	183	26%	<b>0.028</b>
<del>possibly</del> possible	28	13%	32	12%	32	15%	92	13%	0.47
(very)									0.060
<del>probably</del> probable	23	10%	24	9%	10	5%	57	8%	
unknown	20	9%	16	6%	8	4%	44	6%	0.053
cases without SSF	75	34%	97	36%	80	38%	252	36%	0.71
cases with insufficient information	31	14%	28	10%	20	9%	79	11%	0.26
Total cases	222	100%	272	100%	213	100%	707	100%	

SSF=substandard factor

\* Chi-square test

Table 5 Level of care at start of labour, period of death and year of birth in term perinatal mortality deaths

Level of care at start of labour	perinatal death		fetal death		neonatal death	
	n	%	n	%	N	%
primary care	183	19%	101	11%	82	9%
secondary/tertiary care	730	77%	508	54%	222	24%
unknown	30	3%	4	0%	26	3%
Total	943	100%	613	65%	330	35%

  

year	primary care		secondary/tertiary care		Unknown		total
	n	%	n	%	n	%	n
2010	68	21%	227	70%	29	9%	324
2011	69	21%	259	79%	1	0%	329
2012	46	16%	244	84%	0	0%	290
2010-2012	183	19%	730	77%	30	3%	943

  

p-value*	p=0.19	p=0.0001
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\*Chi-square test

**Table 6 Characteristics of term perinatal mortality-deaths in PARS and PRN-Audit versus PRN 2010-2012**

Characteristics	PARS		PRN		p-value*
	n	%	n	%	
gestational age (weeks)					0.91
37.0-40.6	598	85%	930	84%	
≥41.0	109	15%	172	16%	
congenital malformations	135	19%	238	22%	0.20
moment of death					0.40
fetal	440	62%	718	65%	
neonatal	259	37%	384	35%	
unknown period	8	1%			
<b>Total</b>	<b>707</b>	<b>100%</b>	<b>1102</b>	<b>100%</b>	

  

Characteristics	PRN-Audit		PRN		p-value*
	n	%	n	%	
parity 0	450	48%	536	49%	0.68
age mother (years)					
<20	6	1%	11	1%	0.37
≥35	243	26%	292	26%	0.71
non-Caucasian ethnicity	185	20%	257	23%	<b>0.04</b>
congenital malformation	194	21%	238	22%	0.57
period of death					0.94
fetal	613	65%	718	65%	
neonatal	330	35%	384	35%	
birth weight (grams)					
<2000	30	3%	60	5%	<b>0.01</b>
2000-2499	85	9%	98	9%	0.92
≥4500	22	2%	22	2%	0.60
gestational age (weeks)					
37.0-39.6	579	61%	707	64%	0.20
40.0-41.6	341	36%	371	34%	0.12
≥42.0	23	2%	24	2%	0.69
<b>Total</b>	<b>943</b>		<b>1102</b>		

PRN= perinatal registry of The Netherlands

PRN-Audit= perinatal audit registry of The Netherlands

PARS= perinatal audit registry system

\* Chi-square test



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STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	v
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	v
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	v
Objectives	3	State specific objectives, including any prespecified hypotheses	v
Methods			
Study design	4	Present key elements of study design early in the paper	v
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	v
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	v
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	v
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	v
Bias	9	Describe any efforts to address potential sources of bias	v
Study size	10	Explain how the study size was arrived at	v
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	v
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	v
		(b) Describe any methods used to examine subgroups and interactions	n.a.
		(c) Explain how missing data were addressed	n.a.
		(d) If applicable, explain how loss to follow-up was addressed	n.a.
		(e) Describe any sensitivity analyses	n.a.
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	v
		(b) Give reasons for non-participation at each stage	n.a.
		(c) Consider use of a flow diagram	n.a.
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	v
		(b) Indicate number of participants with missing data for each variable of interest	v
		(c) Summarise follow-up time (eg, average and total amount)	v
Outcome data	15*	Report numbers of outcome events or summary measures over time	v
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which	n.a.

		confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	v
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n.a.
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n.a.
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	v
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	v
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	v
Generalisability	21	Discuss the generalisability (external validity) of the study results	v
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	v

\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.